ADDITIONAL WARNING STATEMENTS FOR INCLUSION ON THE LABEL AND/OR IN THE LEAFLET OF CERTAIN MEDICINES

1. PURPOSE

The purpose of this guidance is to set out the warning statements which should appear on the label and/or in the leaflet of certain medicines. UK legislation foresees the need for certain medicines to include warning statements on the label to enable these to be used safely and to best effect.

Previously, a small number of warning statements were included by statute and appeared in Schedule 5 to the Medicines (Marketing Authorisations etc) Regulations 1994 number 3144 [SI 1994/3144]. These applied principally to a small number of medicines available over-the-counter. Many more warning statements were added to the labelling of other medicines through the marketing authorisation rather than through a legislative provision.

As part of the consolidation of the Medicines Act and in line with the better regulation principals operated under Cabinet Office guidelines, with the exception of warning statements to be applied to all medicines containing paracetamol, warning statements will no longer appear on the face of the legislation. Amending legislation is complex and by setting out those medicines and the associated warnings in guidance flexibility can be applied by Marketing Authorisation Holders (MAH) in how these statements are implemented.

2. STATUS

Although having no legal force it is expected that MAHs will apply these warning statements to the labelling and/or the leaflet as appropriate. It will not be necessary to use the wordings proposed verbatim, but it should be borne in mind that many of these forms of words have already been the subject of user testing and are in use (through the British National Formulary) on dispensing labels applied in pharmacies across the UK. Care should be taken to ensure that any deviation from what is set out below does not cause confusion amongst patients.

The warning statements are divided into general and specific categories and for some medicines warnings from both sections may need to be applied.

3. GENERAL WARNING STATEMENTS

For Pharmacy Only (P) medicines where the product would be prescription only if it contained a higher proportion of the active ingredient unless it is an antihistamine or for external use e.g. ibuprofen, codeine, paracetamol This should be placed adjacent to the directions for use or the recommended

dosage:
Warning: Do not take more medicine than the label tells you to.

If the product is for external use only and is and embrocation, liniment, lotion, cream, liquid antiseptic or other liquid preparation or gel. Where the medicine is a Pharmacy Only (P) medicine this statement must appear on the label:

Use this medicine only on your skin.

For medicines which are available as Pharmacy Only. **The letter "P" must appear in a box in which there is no other information.**

For medicines which are available only on prescription. **The letters "POM" must appear in a box in which there is no other information.**

CONTROLLED DRUGS
Medicines which fall to be considered as controlled drugs under the Misuse of Drugs Act 1971 should include the following next to the declaration of the legal status on the labelling. **The letters CD in an inverted triangle.**

ALL MEDICINES

In line with Part 13 of the HMRs a warning that users should "keep out of the sight and reach of children" should appear on the label of all medicines.

In line with Part 13 of the HMRs, a statement encouraging patients to report adverse events which they may experience to the competent authority should appear in the patient information leaflet. In the UK the following form of words should be used:

REPORTING OF SIDE EFFECTS
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.By reporting side effects you can help provide more information on the safety of this medicine.

This should appear at the end of section 4.

MEDICINES SUBJECT TO ADDITIONAL MONITORING
Medicines which appear on the black triangle list published on the MHRA website should include the inverted black triangle immediately after the name in the patient information leaflet followed by the wording in schedule 27 of Human Medicines Regulation 2012 (as amended).

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

The black triangle and the statements should only appear immediately after the declaration of the name of the medicine. The black triangle shall be a black inverted equilateral triangle: the triangle shall be proportional to the font size of the subsequent standardised text and in any case each side of the triangle shall have a minimum length of 5 mm.

4. SPECIFIC STATEMENTS (alphabetical by drug substance)

ADENOSINE

Conditions for P supply

The SPC, label and leaflet should advise the patient:-

- not to take the medicine for longer than 12 weeks without medical advice
- not to take more than the recommended dose

Not for children under 14 years of age.

Label warnings:

Do not take more than the label tells you to
If you do not get better within 12 weeks talk to your doctor
Do not give this medicine to children under 14 years.

ALCLOMETASONE

For topical medicines available as P for over the counter supply the following statements should appear prominently on the label

If you are pregnant talk to your doctor before using.
Apply a thin layer over the affected area of your skin. Do this once or twice a day. If you need to use it for longer than 7 days, stop using and talk to your doctor.

ALOXIPRIN

If the product contains aloxiprin. These statements must be placed prominently on the packaging:

Contains an aspirin derivative

Do not give to children under 16 years of age unless your doctor tells you to.

If you do not get better talk to your doctor

If the product contains aloxiprin these statements must be included on the label where a PIL is NOT separately available.

Aspirin and aspirin derivatives can cause Reye's syndrome when given to children. This is a very rare disease but it can be fatal. Do not give this medicine to children under 16 years of age unless your doctor tells you to.

AMINOPHYLLINE

For P medicines and the product is for asthma or bronchial spasm.

Warning: Talk to your doctor before using this medicine

ANTIDEPRESSANTS (ALL CLASSES)

Suicidal thoughts/behaviour

Patient Information Leaflet
Section 2:

Thoughts of suicide and worsening of your depression or anxiety disorder
If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.
You may be more likely to think like this:
- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**
You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

ARACHIS (PEANUT) OIL

Label:
In the list of ingredients:
Arachis oil (peanut oil)

PIL:
[product] contains arachis oil (also called peanut oil). If you are allergic to peanuts or soya, do not use/take this medicine

ASPIRIN

If the product contains aspirin, unless the product name includes "aspirin" or the product is for external use. These statements must be placed prominently on the packaging:

Contains Aspirin

If you do not get better talk to your doctor

Do not give to children under 16 years of age unless your doctor tells you to.

If the product contains aspirin the following statements must be included on the label where a PIL is NOT separately available:

Aspirin can cause Reye's syndrome when it is given to children. This is a very rare disease but it can be fatal. Do not give aspirin to children under 16 years of age unless your doctor tells you to.

AZELASTINE

For nasal preparations which are available as P for over-the-counter supply for the treatment of seasonal and perennial allergic conjunctivitis:
If you need to use this medicine for longer than 4 weeks, stop using the medicine and talk to your doctor.

BENZODIAZEPINE

PIL:
Secton 1. What this medicine is for
This medicine should be used for as short a time as possible and should not be used for more than four weeks. If used for too long without a break, there is a risk of becoming dependent or of having problems when you stop taking it.

When taking this medicine there is a risk of dependence (a need to keep taking the medicine). The risk increases with the dose and length of treatment period. The risk is greater if you have ever had a history of alcohol or drug abuse.

Section 2. Pregnancy
Do not take X if you are pregnant, might become pregnant or breast-feeding. If you and your doctor decide that you should take this medicine towards the end of your pregnancy (or during labour) this may harm your baby. The baby may have a low temperature, be listless, have breathing problems or difficulty in feeding. Also, if you take this medicine regularly during your pregnancy your baby may get withdrawal symptoms.

Section 3. Stopping X and Withdrawal Effects:
This medicine should not be stopped suddenly; keep taking it until your doctor tells you how to reduce the dose slowly. If you stop taking the tablets suddenly you may experience the following withdrawal effects:

- depression,
- nervousness,

- difficulty in sleeping,
- irritability,
- sweating,
- upset stomach/diarrhoea,
- or the symptoms you are being treated for can come back worse than before.

You may also experience mood changes, anxiety, restlessness and changes in sleep patterns. These effects may occur even after taking low doses for a short period of time.

If you stop taking these tablets suddenly after being treated with high doses of X, you may experience confusion, hallucinations, shaking, faster heartbeat or fits.

Withdrawal may also cause unusual behaviour including aggressive outbursts, excitement or depression with suicidal thoughts or actions**.**

BIFONAZOLE

For topical products available GSL for athlete's foot:
Only use this to treat athlete's foot. If you are unsure if you have athlete's foot talk to your doctor or pharmacist first. If you need to use the cream for more than 7 days stop using it and talk to your doctor.

β-BLOCKERS

Label:
Do not take this medicine if you have wheezing or asthma.

PIL:
Do not take this medicine if you have wheezing or asthma. Talk to your doctor or pharmacist first.

BUDESONIDE

For products available as P medicines over-the-counter for nasal administration to treat seasonal allergic rhinitis:
If you need to use this medicine for more than 14 days stop using it and talk to your doctor.

BUPRENORPHINE

3 DAY PATCHES

PARTICULARS TO APPEAR ON OUTER PACKAGING

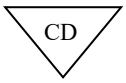
Front of carton

Add the following text - prominently

Change the patch after 72 hours

Back of carton

Add the following text



POM

Read the package leaflet before use

Make a note of the day, date and time that you apply the first patch. Change the patch at the same time of day 72 hours (3 days) later:

Apply	Mon	Tue	Wed	Thu	Fri	Sat	Sun
	↓	↓	↓	↓	↓	↓	↓
Change	Thu	Fri	Sat	Sun	Mon	Tue	Wed

Time:

Sufficient space should be provided to accommodate a standard dispensing label of 70 x 35 mm.

PATIENT INFORMATION LEAFLET

Headlines

Headline information should be presented prominently at the beginning of the PIL.

- These patches contain a strong pain killer
- Ensure that old patches are removed before applying a new one
- Patches must not be cut
- Do not expose the patches to a heat source (such as a hot water bottle)
- Do not soak in a hot bath or take a hot shower whilst wearing a patch.
- If you develop a fever tell your doctor immediately
- Follow the dosage instructions carefully and only change your patch at the same time of day 72 hours (3 days) later
- If your breathing becomes shallow and weak take the patch off and seek medical help

Section 2 – Warnings and Precautions

Driving and using machinery

Add the following text

[Product name] can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:

  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Section 3 – How to use

Add the following text

The following table shows you when to change your patch:

Apply your patch on		**Change your patch at the same time of day on**
Monday	→	Thursday
Tuesday	→	Friday
Wednesday	→	Saturday
Thursday	→	Sunday
Friday	→	Monday
Saturday	→	Tuesday
Sunday	→	Wednesday

4 DAY PATCHES

PARTICULARS TO APPEAR ON OUTER PACKAGING

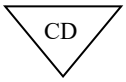
Front of carton

Add the following text - prominently

Change the patch twice a week

Back of carton

Add the following text



POM

Read the package leaflet before use

Choose the pair of days / times that is most convenient for you. Make a note of the day, date and time that you apply the first patch. The patch should then be changed twice a week at the chosen times:

Apply / change	**Morning**	Mon	Tue	Wed	Thu	Fri	Sat	Sun
		↺	↺	↺	↺	↺	↺	↺
	Evening	Thu	Fri	Sat	Sun	Mon	Tue	Wed
	Time:							

Sufficient space should be provided to accommodate a standard dispensing label of 70 x 35 mm.

PATIENT INFORMATION LEAFLET

Headlines

Headline information should be presented prominently at the beginning of the PIL.

- These patches contain a strong pain killer
- Ensure that old patches are removed before applying a new one
- Patches must not be cut
- Do not expose the patches to a heat source (such as a hot water bottle)
- Do not soak in a hot bath or take a hot shower whilst wearing a patch.
- If you develop a fever tell your doctor immediately
- Follow the dosage instructions carefully and only change your patch twice a week at the chosen times
- If your breathing becomes shallow and weak take the patch off and seek medical help

Section 2 – Warnings and Precautions

Driving and using machinery

Add the following text

[Product name] can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.

- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Section 3 – How to use	

Add the following text

The following table shows you when to change your patch:

Apply/change your patch in morning of		**Apply/change your patch in evening of**
Monday	⇆	Thursday
Tuesday	⇆	Friday
Wednesday	⇆	Saturday
Thursday	⇆	Sunday
Friday	⇆	Monday
Saturday	⇆	Tuesday
Sunday	⇆	Wednesday

7 DAY PATCHES

PARTICULARS TO APPEAR ON OUTER PACKAGING

Front of carton

Add the following text - prominently

Change the patch after 7 days

Back of carton

Add the following text

CD POM

Read the package leaflet before use

Make a note of the day, date and time when you apply the first patch. Change the patch on the same day and at the same time 7 days later:

Apply / Change	Mon	Tue	Wed	Thu	Fri	Sat	Sun

Time:

Disposal after use**:** Keep the sachet after removing the patch inside. Keep it to put your used patch in. As soon as you take the patch off, fold it firmly in half (sticky sides together) and put it back in the sachet. Either discard in the bin with the household rubbish or return to the pharmacy.

Keep out of the sight and reach of children

This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how if makes you feel. See the leaflet inside for more information.

Sufficient space should be provided to accommodate a standard dispensing label of 70 x 35 mm.

PATIENT INFORMATION LEAFLET

Headlines

Headline information should be presented prominently at the beginning of the PIL.

- These patches contain a strong pain killer
- Ensure that old patches are removed before applying a new one
- Patches must not be cut
- Do not expose the patches to a heat source (such as a hot water bottle)
- Do not soak in a hot bath or take a hot shower whilst wearing a patch.
- If you develop a fever tell your doctor immediately
- Follow the dosage instructions carefully and only change your patch on the same day and at the same time 7 days later
- If your breathing becomes shallow and weak take the patch off and seek medical help

Section 2 – Warnings and Precautions

Driving and using machinery

Add the following text

[Product name] can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

CHLORAMPHENICOL

For medicines available for P supply the following statements should appear prominently on the label:

If you do not get better within 48 hours talk to your doctor.
If your eye gets worse see your doctor straight away.
Do not use these eye drops if you are allergic to chloramphenicol or anything else in the drops.
After five days, throw away any eye drops left.

CIMETIDINE

For medicines available as P for over-the-counter supply:
This medicine may be taken for up to 14 days. If you need to take it for longer than 14 days or your symptoms come back stop taking the medicine and talk to your doctor.

CLOBETASONE BUTYRATE

For medicines available for P supply the following statements should appear prominently on the label:

If you are pregnant talk to your doctor before using this medicine.
Apply a thin layer over the affected area of your skin. Do this once or twice a day. If you need to use it for longer than 7 days, stop using the product and talk to your doctor.

CLOTRIMAZOLE

See imidazoles

CODEINE & DIHYDROCODEINE

For medicines which contain codeine or dihydrocodeine and are available for Pharmacy supply [P]:

But see entry for Opioids below

LABELLING

Front of Pack

- Can cause addiction
- Contains opioid
- For three days use only

These requirements are in addition to the normal statutory provisions and should be prominently displayed.

This information will also be included in section 4.4 of the SmPC under the heading “The label will state”.

Back of Pack

- List of indications as agreed in 4.1 of the SmPC
- If you need to take this medicine continuously for more than three days you should see your doctor or pharmacist
- This medicine contains codeine [or dihydrocodeine] which can cause addiction if you take it continuously for more than three days. If you take this medicine for headaches for more than three days it can make them worse

These requirements are in addition to the normal statutory provisions and should be prominently displayed.

This information will also be included in section 4.4 of the SmPC under the heading “The label will state”.

LEAFLET

Headlines section (to be prominently displayed)

- This medicine can only be used for …….(indications)
- You should only take this product for a maximum of three days at a time. If you need to take it for longer than three days you should see your doctor or pharmacist for advice
- This medicine contains codeine [or dihydrocodeine] which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it
- If you take this medicine for headaches for more than three days it can make them worse

Section 1: What the medicine is for

- Succinct description of the indications from 4.1 of the SmPC

Section 2: Before taking

- This medicine contains codeine [or dihydrocodeine] which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it
- If you take a painkiller for headaches for more than three days it can make them worse

Pregnancy and Breast-feeding (for codeine only)
Usually it is safe to take "X" while breast-feeding as the levels of codeine in breast milk are too low to cause your baby any problems. However, some women who are at increased risk of developing side effects at any dose may have higher levels of codeine in their breast milk. If any of the following side effects develop in you or your baby stop taking this medicine and speak to your doctor at once: feeling sick, being sick, constipation, poor appetite, feeling tired or sleeping for longer than usual, shallow or slow breathing.

Section 3: Dosage
- Do not take for more than 3 days. If you need to use this medicine for more than three days you should speak to your doctor or pharmacist
- This medicine contains codeine [or dihydrocodeine] and can cause addiction if you take it continuously for more than three days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms

Section 4: Side effects
Some people may have side-effects when taking this medicine.

REPORTING OF SIDE EFFECTS
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.By reporting side effects you can help provide more information on the safety of this medicine.

NEW SECTION: How do I know if I am addicted?
If you take the medicine according to the instructions on the pack it is unlikely that you will become addicted to the medicine. However, if the following apply to you it is important that you talk to your doctor:
- You need to take the medicine for longer periods of time
- You need to take more than the recommended dose
- When you stop taking the medicine you feel very unwell but you feel better if you start taking the medicine again

For medicines which contain codeine or dihydrocodeine and are available on prescription only [POM]

The label will state (**To be displayed prominently on outer pack):**

- Can cause addiction
- Contains opioid
- Do not take for longer than directed by your prescriber as taking codeine/dihydrocodeine regularly for a long time can lead to addiction.

The leaflet will state in a prominent position in the 'before taking' section:

- Do not take for longer than directed by your prescriber
- Taking codeine/dihydrocodeine (DHC) regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets.
- Taking a painkiller for headaches too often or for too long can make them worse.

COLCHICINE

Outer and immediate packaging for 1000microgram strength tablets

HIGH STRENGTH – CHECK DOSE!

The warning should appear in the same field of view, in all places where the wording 'colchicine' and '1000 mcg' are presented. The warning should appear in a prominent box, using bold lettering and a contrasting colour to the rest of the pack

DEXAMETHASONE

The information below should be included in the PIL as set out in the sections itemised.

Dexamethasone – Headlines

- **Dexamethasone is a steroid medicine,** prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor - you may need to reduce the dose gradually.
- **Dexamethasone can cause side effects in some people** (read section x below). Some problems such as mood changes (feeling depressed, or 'high'), or stomach problems can happen straight away. If you feel unwell in any way, keep taking your tablets, but **see your doctor straight away.**
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs, or developing a rounder face (read section x for more information).
- **If you take it for more than 3 weeks, you will get a blue 'steroid card':** always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chicken-pox or shingles**, if you

have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, **see your doctor straight away.**

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you. **This leaflet was last updated on xx/xx/xx**

Section 1.
Benefit Information to be included

Dexamethasone belongs to a group of medicines called steroids. Their full name is *corticosteroids*. These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as dexamethasone) is an effective way to treat various illnesses involving inflammation in the body. Dexamethasone reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Section 2.
Before you take dexamethasone

Check with your doctor first

- **If you have ever had severe depression** or manic-depression *(bipolar disorder)*. This includes having had depression before while taking steroid medicines like dexamethasone.
- **If any of your close family** has had these illnesses.

If either of these applies to you, **talk to a doctor before taking dexamethasone.**

Mental problems while taking dexamethasone
Mental health problems can happen while taking steroids like dexamethasone (see also section 4 *Possible Side Effects*)

- These illnesses can be serious
- Usually they start within a few days or weeks of starting the medicine.
- They may be more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen, they might need treatment.

Talk to a doctor if you (or someone taking this medicine), show any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide and when doses are being lowered or stopped. In a few cases, mental problems have happened during this time.

Section 4.
Possible side effects

Serious effects: tell a doctor straight away
Steroids including dexamethasone can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like dexamethasone.

- Feeling depressed, including thinking about suicide.
- Feeling high (mania) or moods that go up and down
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused

and losing your memory.
- Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

If you notice any of these problems **talk to a doctor straight away.**

DIAMORPHINE

See MORPHINE

DICLOFENAC

Prescription Medicines – oral formulations and suppositories

The Patient Information Leaflet (PIL) should be revised. The following wording should be added to the PIL:
Section 2 "What you need to know before you take X"

Do not take X if you
- Have had a heart attack, a stroke, a mini-stroke (TIA), blood clots or had a heart bypass
- have or have ever had a stomach ulcer, perforation or bleeding
- are allergic to diclofenac or any other ingredient of the product, aspirin, ibuprofen or other related painkillers
- are taking other NSAID painkillers, or aspirin
- are pregnant or breastfeeding

Speak to a pharmacist or your doctor before taking this product if
- you have asthma, diabetes, high cholesterol, angina, high blood pressure, liver, kidney or bowel problems
- there is a chance you may be pregnant
- you smoke

Topical medicines available as P (over the counter)

The label will include:
Read the enclosed leaflet before taking this product.
Do not use if you
- are allergic to diclofenac or any other ingredient of the product, aspirin, ibuprofen or other related painkillers
- are taking other NSAID painkillers, or aspirin
- are in the last three months of pregnancy

Speak to a pharmacist or your doctor before using this product if
- have or have ever had a stomach ulcer, perforation or bleeding
- you have asthma, diabetes, high cholesterol, angina, high blood pressure, liver, kidney or bowel problems
- there is a chance you may be pregnant or you are breastfeeding
- you smoke

PIL: For systemic formulations only

1. Dosage:

Adults, the elderly and children over 12 years:

- This medicine is for short-term use only.
- Take the lowest dose for the shortest time necessary.
- Do not take 'X' for longer than 3 days.

If you do not get better, or get worse, talk to your doctor. They will tell you if it is safe to carry on taking the medicine.

2. Female fertility:

X belongs to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking the medicine. It is unlikely that if you only take X occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant talk to your doctor before taking this medicine.

3. Low dose aspirin

Do not take if you are taking more than 75mg of aspirin a day. If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take [PRODUCT].

4. Gastrointestinal side effects:

If you get any of the following at any time during your treatment
STOP TAKING, and get medical help straight away:

- Pass blood in your stools or motions
- Pass black tarry stools or motions
- Vomit any blood or dark particles that look like coffee grounds

STOP TAKING and tell your doctor if you experience:

- Indigestion or heartburn

Pains in your stomach (abdomen) or other abnormal stomach problems.

DIPHENOXYLATE HYDROCHLORIDE

For medicines available in combination with atropine as P for over-the-counter use:

If you need to use this medicine for more than 24 hours stop taking it and talk to your doctor. This medicine will only treat your symptoms. You need to make sure you take rehydration therapy as well.

DOPAMINERGIC MEDICINES

PIL: **For medicines which contain bromocriptine, cabergoline, levodopa, pergolide, piribedil, pramipexole and ropinirole (to treat Parkinson's disease)**

1. Warnings and precautions section:

This medicine can make you feel very sleepy during the day and can also make you fall asleep suddenly. You should not drive, use tools or operate machines.

2. Driving and using machines:

[Product] can make you feel very sleepy during the day and can also make you fall asleep suddenly. You should not drive, use tools or operate machines as you may put yourself or others at risk of serious injury.

3. Side effects:

This medicine can make you feel very sleepy and can also make you fall asleep suddenly.

PIL: **For medicines which contain apomorphine, α-dihydroergocryptine, lisuride and quinagolide (to treat Parkinson's disease**)

1. Warnings and precautions section:

This medicine can make you feel very sleepy during the day. You should not drive, use tools or operate machines.

2. Driving and using machines:

[Product] can make you feel very sleepy during the day. You should not drive, use tools or operate machines as you may put yourself or others at risk of serious injury.

3. Side effects:

This medicine can make you feel very sleepy

ECONAZOLE

See imidazoles

EPHEDRINE

For P medicines and the product is for asthma or bronchial spasm.

Warning: Talk to your doctor before using this medicine.

FAMOTIDINE

For medicines available as P for over-the-counter supply:
This medicine may be taken for up to 14 days. If you need to take it for longer than 14 days or your symptoms come back stop taking the medicine and talk to your doctor.

FENTANYL

FRONT OF PACK

- Can cause addiction
- Contains opioid
- For three days use only

These requirements are in addition to the normal statutory provisions and should be prominently displayed.

BACK OF CARTON

Read the package leaflet before use

How to use the patches/medicine
[Product name] should be worn continuously for 3 days (72 hours).
It is important to change your patch on the correct day at the same time that it was applied.

Disposal after use**:** Keep the pouch after removing the patch inside. Keep it to put your used patch in. As soon as you take the patch off, fold it firmly in half (sticky sides together) and put it back in the pouch. Either discard in the bin with the household rubbish or return to the pharmacy.

Keep out of the reach and sight of children

Sufficient space should be provided to accommodate a standard dispensing label of 70 x 30 mm.

FRONT OF POUCH

The front of the pouch should be fully compliant with Article 55(3)

BACK OF POUCH

Read the leaflet before use. Dosage: as directed by your doctor.

Remove your old patch before applying a new one on a new area of skin.
Apply a new patch every 3 days (72 hours)

Opening instructions *[maximum for four bullet points, they should be succinct in content]*

- Gently tear open the pouch at the tear notch and remove the edge of the pouch completely.
- Grasp both sides of the opened pouch and pull apart completely.
- Take out the patch and use it straight away.
- Never divide or cut the patch. Do not use the patch if it looks damaged.

Disposal after use: Keep the pouch after removing the patch inside. Keep it to put your used patch in. As soon as you take the patch off, fold it firmly in half (sticky sides together) and put it back in the pouch. Either discard in the bin with the household rubbish or return to the pharmacy.

Keep out of the reach and sight of children

PATIENT INFORMATION LEAFLET

Headlines

Headline information should be presented prominently at the beginning of the PIL.

Add the following text

- These patches contain a strong pain killer.
- Ensure that old patches are removed before applying a new one.
- Patches must not be cut.
- Do not expose the patches to a heat source (such as a hot water bottle).
- If you develop a fever tell your doctor immediately.
- Follow the dosage instructions carefully and only change your patch every 72 hours.
- If your breathing becomes shallow and weak take the patch off and seek medical help.

Section 2 – Take special care

Key words in the following sentences should be highlighted

Add the following text

- If you **develop** a **fever** while wearing [Product name], tell your doctor as this may affect the way the medicine passes through your skin.
- Do not **expose** the patch to a direct **heat** source such as **heating pads**, hot water bottles, **electric blankets**, heat lamps, **saunas** and hot whirlpool spa baths. These may affect the way the medicine works.

Section 3 – How to use	

As the dosage of fentanyl is determined on a case by case basis all MAs should remove dosage information.

Add the following text

Using and changing the patches

- There is enough medicine in each patch to last **3 days (72 hours)**
- You should change your patch every third day, unless your doctor has told you otherwise.
- Always **remove** the old **patch** before applying the **new one**.
- Always change your patch at the same time of day every **3 days (72 hours)**
- Make a note of the **day**, **date** and **time** you apply a patch, to remind you when you need to change your patch.
- The following table shows you which day of the week to change your patch.

Apply you patch on day the same time on		**Change your patch at**
Monday	→	Thursday
Tuesday	→	Friday
Wednesday	→	Saturday
Thursday	→	Sunday
Friday	→	Monday
Saturday	→	Tuesday
Sunday	→	Wednesday

Where to apply the patch

Adults

- Apply the patch on a flat part of your upper body or arm.

Children

- Always apply the patch to the upper back to make it difficult for your child to reach it or take it off.
- Every so often check that the patch remains stuck to the skin.
- It is important you child does not remove the patch and put it in their mouth as this could be life-threatening or even fatal.
- It may take some time before the patch becomes fully effective. Therefore, your child might need additional painkillers until the patches become effective. Your doctor will advise you on this if it is needed.
- Children need to be monitored very closely for 48 hours after:
  - The first patch has been put on
  - A higher dose patch has been put on

For you and your child, **do not apply the patch on**:
- The same place twice in a row
- Sensitive areas that you move a lot, cuts, spots or other skin blemishes.

- Skin that is very hairy, if there is a hair, do not shave it (shaving irritates the skin). Instead clip the hair as close to the skin as possible.

You should allow several days to pass before you put a new patch on the same area of skin.

Putting a patch on

Step 1: Preparing the skin

- Make sure your skin is completely clean, dry and cool before you put the patch on.
- If you need to clean the skin, just use cold water.
- Do not use soap or any other cleansers, creams, moisturisers, oils or talc before applying the patch.
- Do not stick a patch on straight after a hot bath or shower.

Step 2: Open the pouch

- Each patch is sealed in its own pouch
- Tear or cut off the edge of the pouch completely (if you use scissors, cut close to the sealed edge of the pouch to avoid damaging the patch)
- Grasp both sides of the opened pouch and pull apart
- Take the patch out and use it straight away
- Keep the empty pouch to dispose of the used patch later
- Use each patch once only
- Do not take the patch out of its pouch until you are ready to use it
- Inspect the patch for any damage
- Do not use the patch if it has been divided, cut or looks damaged
- Never divide or cut the patch

Step 3: Peel and press

- Make sure that the patch will be covered by loose clothing and not stuck under a tight or elasticated band.
- Carefully peel one half of the shiny plastic backing away from the centre of the patch. Try not to touch the sticky side of the patch.
- Press this sticky part of the patch onto the skin.
- Remove the other part of the backing and press the whole patch onto the skin with the palm of your hand.
- Hold for at least 30 seconds. Make sure it sticks well, especially the edges.

Step 4: Disposing of the Patch

- As soon as you take the patch off, fold it firmly in half so that the sticky side sticks to itself.
- Put it back in its original pouch and put the pouch in the bin with your household rubbish.

- Even used patches contain some medicine which may harm children, so keep your used patches out of the reach and sight of children.

Step 5: Wash

Wash your hands afterwards with clean water.

More about using [Product name] patches

How quickly will the patches work?

- It may take up to a day before your first patch is working completely.
- Your doctor may give you extra painkillers for your first day or so.
- After this, the patch should help to relive pain continuously so that you can stop taking other painkillers. However, your doctor may still prescribe extra painkillers from time to time.

If you forget to change the patch

- If you forget, change your patch, as soon as you remember and make a note of the day and time. Change the patch again after **3 days (72 hours)** as usual.
- If you are very late changing your patch, you should talk to your doctor because you might need extra painkillers, but do not apply an extra patch.

If you use too many patches or the wrong strength patch

- If you have stuck on too many patches or the wrong strength patch, take the patches off and contact a doctor or the nearest hospital straight away.

Signs of an overdose include **trouble breathing** or **shallow breathing**, tiredness, extreme sleepiness, being unable to think clearly, walk or talk normally and feeling faint, dizzy or confused.

If the patch falls off

- If the patch falls off before it needs changing, stick a new one on straight away and make a note of the day and time. Use a new area on:
    - On your upper body or arm
    - Your child's upper back
- Leave another **3 days (72 hours)** before changing the new patch as usual
- If your patch keeps falling off, talk to your doctor, nurse or pharmacist.

If a patch sticks to another person

- Only use the patch on the skin of the person who it is prescribed for.
- Make sure the patch does not get rubbed off and sticks to your partner, especially in bed.
- If a patch accidentally sticks to another person, take it off straight away and talk to your doctor.

If your pain gets worse

- If your pain gets worse while you are using these patches, your doctor may try a higher strength patch, or give you extra painkillers (or both)
- If increasing the strength of the patch does not help, your doctor may stop the patches.

If you want to stop using the patches

- Talk to your doctor before you stop using these patches.
- If you have been using them for some time your body may have got used to them. Stopping suddenly may make you feel unwell.
- If you stop using the patches, don't start again without asking your doctor first. You might need a different strength patch when you restart.

Section 4 – Possible side effects

All serious/stop taking adverse events should be presented at the beginning of section 4 to aid patient/carers identification of life threatening symptoms.

Take the patch off and tell your doctor or go to your nearest hospital straight away if you notice or suspect any of the following. You may need urgent medical treatment.

Feeling unusually drowsy, breathing more slowly or weakly than expected. Very rarely these breathing difficulties can be life threatening or even fatal especially in people who have not used strong opioid painkillers before. If you notice any of the above, follow the guidance above and keep moving as much as possible.

FENTICONAZOLE NITRATE

See imidazoles

FLUCONAZOLE NITRATE

See imidazoles

FLUNISOLIDE

For nasal products available as P for the prevention and treatment of seasonal allergic rhinitis, including hayfever:
If you need to use this medicine for longer than two weeks, stop using and talk to your doctor.

FLURBIPROFEN

For medicines which contain flurbiprofen in a lozenge formulation intended for use in sore throats and available as a pharmacy medicine [P]:

Label:
Read the enclosed leaflet before taking this medicine.
Do not take if you

- have ever had a stomach ulcer, perforation or bleeding
- are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers
- are taking other NSAID painkillers, or aspirin with a daily dose above 75mg
-

Speak to a pharmacist or your doctor before taking this medicine if you

- have asthma, diabetes, high cholesterol, high blood pressure, had a stroke, liver, heart, kidney or bowel problems
- are a smoker
- are pregnant

If you do not get better in X days, talk to your doctor.

PIL:

1. POSOLOGY:

Adults, the elderly and children over 12 years: This medicine is intended for short-term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms. You should not take 'X' for longer than 10 days. If your condition continues or gets worse talk to your doctor, who may tell you to carry on taking the medicine.

2. FEMALE FERTILITY:

X belongs to a group of medicines which may affect fertility in women. This effect is reversible when you stop taking the medicine. It is unlikely that if you only take X occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant talk to your doctor before taking this medicine.

3. LOW DOSE ASPIRIN

Do not take if you are taking aspirin at doses of above 75mg daily. If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take [PRODUCT].

4. GASTROINTESTINAL EFFECTS:

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds

STOP TAKING the medicine and tell your doctor if you experience:
Indigestion or heartburn
abdominal pain (pains in your stomach) or other abnormal stomach symptoms

FLUTICASONE

For medicines available as P for the prevention and treatment of allergic rhinitis:
This medicine can be used for up to 3 months. However, if you do not improve in 7 days you should stop using the product and talk to your doctor.

HEPARINOID

For medicines available as GSL for the relief of bruises, sprains and soft tissue injuries:
If there is no improvement in your condition within 5 days stop using the product and talk to your doctor.

HEXACHLOROPHANE

Either:
Do not use this medicine on babies

Or:
Do not use this medicine on children under two years of age unless your doctor tells you to.

HYDROCORTISONE & HYDROCORTISONE ACETATE

For medicines available as P and/or GSL over the counter supply the following statements should appear prominently on the label

If you are pregnant talk to your doctor before using.
Apply a thin layer over the affected area of your skin. Do this once or twice a day. If you need to use it longer than 7 days, stop using and talk to your doctor.

HYDROXYZINE HYDROCHLORIDE

For medicines which are available for pharmacy only [P] supply the following statements should be prominently displayed:

Label:

This medicine may make you feel sleepy. If this happens do not drive or

use tools or machines. Do not drink alcohol.

Leaflet:

Only use this medicine in adults and children aged 6 years and above.
Do not take this medicine for longer than 10 days.
If you do not get better talk to your doctor.

HYOSCINE BUTYLBROMIDE

For medicines available over the counter for pharmacy only [P] or general sales list [GSL] supply:

Additional warnings for irritable bowel syndrome (to be included in the patient information leaflet)

If this is the first time you have had these symptoms, talk to your doctor before using this medicine. This is to make sure it is suitable for you.

Do not use this medicine without talking to your doctor if you:

Are over 40 years of age
Have passed blood in your stools or motions
Are feeling sick or being sick
Have lost your appetite or lost weight
Look pale and feel tired
Are very constipated
Have a fever
Have recently been travelling abroad
Are or may be pregnant
Have abnormal vaginal bleeding or discharge
Have difficulty or pain when passing water

Talk to your doctor if you get new symptoms, your symptoms get worse or if they do not improve after 2 weeks of treatment.

IBUPROFEN

For medicines which contain ibuprofen, are for oral use and are available over-the-counter as pharmacy only [P] or general sales list [GSL] supply.

Label:
Read the enclosed leaflet before taking this medicine.
Do not take if you

- have ever had a stomach ulcer, perforation or bleeding
- are allergic to ibuprofen (or anything else in this medicine), aspirin or other related painkillers
- are taking other NSAID painkillers, or aspirin with a daily dose above 75mg
- are in the last 3 months of pregnancy.
-

Talk to a pharmacist or your doctor before taking if you

- have asthma, diabetes,high cholesterol, high blood pressure, had a

stroke, liver, heart, kidney or bowel problems
- are a smoker
- are pregnant

If symptoms do not get better or get worse or if you get new symptoms, talk to your doctor.

PIL:

1. POSOLOGY:

Adults, the elderly and children over 12 years:
- This medicine is for short-term use only.
- Take the lowest dose for the shortest time necessary.
- Do not take 'X' for longer than 10 days.

If you do not get better, or get worse, talk to your doctor. They will tell you if it is safe to carry on taking the medicine.

2. FEMALE FERTILITY:

X belongs to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking the medicine. It is unlikely that if you only take X occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant talk to your doctor before taking this medicine.

3. LOW DOSE ASPIRIN

Do not take if you are taking more than 75mg of aspirin a day. If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take [PRODUCT].

4. GASTROINTESTINAL EFFECTS:

If you get any of the following at any time during your treatment
STOP TAKING, and get medical help straight away:
- Pass blood in your stools or motions
- Pass black tarry stools or motions
- Vomit any blood or dark particles that look like coffee grounds

STOP TAKING and tell your doctor if you experience:
- Indigestion or heartburn
- Pains in your stomach (abdomen) or other abnormal stomach problems.

IMIDAZOLE

The SmPC and patient information leaflet for an OTC product containing an imidazole antifungal for vaginal candidiasis should normally contain the following information:

Talk to your doctor if you

- Have ever had a sexually transmitted disease (STD)
- Have had a partner with a sexually transmitted disease
- Have had thrush more than twice in the last 6 months
- Are allergic to [active substance] or to other vaginal medicines to treat thrush
- Are pregnant or may be pregnant
- Have any unusual or irregular vaginal bleeding or you have any vulval or vaginal sores, ulcers or blisters
- Have blood stained vaginal discharge
- Have any lower stomach pain or pain when passing water
- Have any side effects such as redness, irritation or swelling associated with the treatment

Also talk to your doctor if you have not improved after 7 days

IRON-CONTAINING PRODUCTS (>24mg elemental iron)

For medicines which contain >24mg of elemental iron and are available as either pharmacy only [P] or prescription only medicines [POM]. The following statements should appear prominently on the front face of the packaging

Important warning: Contains iron. Keep out of the reach and sight of children, as overdose may be fatal.

ISOCONAZOLE

See imidazoles

KETOCONAZOLE

See imidazoles

KETOPROFEN GEL

There is a risk of photosensitivity with use of Ketoprofen gel. The following information along with the symbol should appear on the labelling and in section 2 of the patient information leaflet:

Protect your skin from sunlight even on a bright but cloudy day. Do not use sunbeds. This applies during treatment and for two weeks after stopping.

LEVOCABASTINE HYDROCHLORIDE

For P medicines available for the treatment of hayfever
You may use this medicine for up to 4 weeks. You should only use it if you have hayfever symptoms. If you do not improve within 3 days stop using the medicine and talk to your doctor.

LOPERAMIDE

For medicines available as P or GSL the leaflet should include the following information:

For acute diarrhoeal
If you are taking loperamide for acute diarrhoea you should stop taking the medicine and talk to your doctor if you do not get better within 48 hours.

For acute episodes of diarrhoea associated with irritable bowel syndrome:
You should only use this medicine to treat acute episodes of diarrhoea associated with IBS if your doctor has told you that you suffer from IBS.

If you are taking loperamide for episodes of IBS you should stop taking the medicine if you do not get better within 48 hours or if the pattern of your symptoms change or repeated episodes of diarrhoea continue for more than two weeks.

If this is the first time you have had these symptoms talk to your doctor before using this medicine. This is to make sure it is suitable for you.

Do not use this medicine without talking to your doctor if you:

- Are over 40 years of age
- Have passed blood in your stools or motions
- Are feeling sick or being sick
- Have lost your appetite or lost weight
- Look pale and feel tired
- Are very constipated
- Have a fever
- Have recently been travelling abroad
- Are or may be pregnant
- Have abnormal vaginal bleeding or discharge
- Have difficulty or pain when passing water

Talk to your doctor if you get new symptoms, your symptoms get worse or if they do not improve after 2 weeks of treatment.

LORATADINE

Although loratadine may be used in children aged over 2 years of age all formulations are not suitable for all age ranges. For example, the 10mg tablets are only suitable for children who weigh more than 30kg in addition to being over 2 years of age. As a general rule children who are over 30kg would usually be over 9 years of age. The following information should appear on the labelling and in the patient information leaflet of loratadine 10mg tablets:

LABEL
Giving this medicine to children:
You must know how much your child weighs. As a guide a child 9 years old will weigh about 30kg (4 and a half stone). Do not give to children who weigh less than 30kg. Do not give to children under 2 years of age. A liquid presentation of loratadine may be more suitable for children.

LEAFLET
Do not give to children under 2 years of age or to children weighing less than 30kg. As a guide, the average 9 year old child weighs approximately 30 kg (equivalent to 4 and a half stone). Check your child's weight if you are not sure. For children over 2 years but who weigh less than 30kg a syrup form of this medicine may be more suitable.

MEBEVERINE HYDROCHLORIDE

For medicines which are available over-the-counter for pharmacy only [P] or general sales list [GSL] supply.

Additional warnings (to be included in the patient information leaflet)

If this is the first time you have had these symptoms talk to your doctor before using this medicine. This is to make sure it is suitable for you.

Do not use this medicine without talking to your doctor if you:

- Are over 40 years of age
- Have passed blood in your stools or motions
- Are feeling sick or being sick
- Have lost your appetite or lost weight
- Look pale and feel tired
- Are very constipated
- Have a fever
- Have recently been travelling abroad
- Are or may be pregnant
- Have abnormal vaginal bleeding or discharge
- Have difficulty or pain when passing water

Talk to your doctor if you get new symptoms, your symptoms get worse or if they do not improve after 2 weeks of treatment.

MEPYRAMINE

For topical medicines available GSL for bites and stings:
Do not use on cut, grazed or sunburnt skin. Apply a thin layer over a small area of the affected skin. If you need to use this medicine for more than 3 days stop using and talk to your doctor.

METHOTREXATE

For medicines which contain methotrexate and are intended for oral use the following statements should be prominently displayed on the labelling:

Use as directed by a physician.

Prominently on the front face of the packaging:
Check dose and frequency - Methotrexate is usually taken once a week.

MICONAZOLE

See imidazoles

MONTELUKAST

To enable patients/carers to be sure that the right dose is being used for the correct age group tablet presentations must include the following information on the front face of the labelling:

Montelukast 4mg tablets
For children 2 to 5 years of age

Montelukast 5mg tablets
For children 6 to 14 years of age

MORPHINE/DIAMORPHINE

CARTON – FRONT FACE

Front of Pack (OTC medicines)

- Can cause addiction
- Contains opioid
- For three days use only

Front of Pack (POM medicines)

- Can cause addiction
- Contains opioid

These requirements are in addition to the normal statutory provisions and should be prominently displayed.

LICENSED PRODUCT NAME*
& licensed pharmaceutical form (unless part of product name)

‘x’mg in ‘y’ml

Caution – high dose**

Route of administration : *[state SC / IM / IV]*
Protect from light
Please read ampoule label carefully
‘n’ x ‘y’ampoules

Note: MA holders that have more than one strength of morphine/diamorphine for injection should ensure clear differentiation between the packs by the judicious use of colour.

* The product name should include the unit dose per unit volume, e.g. 30mg / ml. If this is not the same as the total dose per total volume, then the latter should be included on a separate line, as ‘x’mg in ‘y’ml.
** Applicable for strengths of 30mg and above.
Please also note - this statement should be printed in red text surrounded by a red box.

CARTON – SIDE FACES

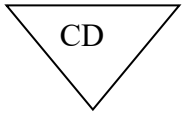
LICENSED PRODUCT NAME
& licensed pharmaceutical form (unless part of name)

‘X’mg/ml
(unit dose/unit vol)

‘x’mg in ‘y’ml (* total strength in total volume see note above)
‘n’ x ‘y’ ml ampoules

CARTON – BACK FACE

In addition to the statutory information, the strength should also be stated on the back of the carton, and highlighted to ensure it stands out, as stated above for top and side of carton.



† The inclusion of the 'controlled drug' abbreviation symbol is voluntary. Please note that if it is added to the carton, it should appear on the back of the carton in an inverted triangle, as shown here.

AMPOULE LABEL

LICENSED PRODUCT NAME*

'x'mg / 'y'ml

Route of administration
Pack size *(e.g. 1ml, 2ml etc.)*
PL *****/****
MAH name/logo‡
BN:
Exp:

* The product name should include the unit dose per unit volume, e.g. 30mg / ml. If this is not the same as the total dose per total volume, then the latter should be included on a separate line, as 'x'mg in 'y'ml.

‡ in line with Best Practice Guidance.

Note: Ampoule text must **not** be black text on a yellow background, nor should there be any other background symbols.

Instead, ensure that the colour scheme used on the cartons (i.e. the outer label) is also applied to the ampoule label (i.e. the inner label) for the corresponding strength.

Key:
'n' = number of ampoules in the carton
'x' = strength of morphine sulphate.
'y' = total volume

NAPROXEN

For medicines which contain naproxen, are for oral use and are available over-the-counter as pharmacy only [P] supply.

Label:
Read the enclosed leaflet before taking this medicine.
Do not take if you

- have ever had a stomach ulcer, perforation or bleeding
- are allergic to ibuprofen (or anything else in this medicine), aspirin or other related painkillers
- are taking other NSAID painkillers, or aspirin with a daily dose above 75mg

- are in the last 3 months of pregnancy.
-

Talk to a pharmacist or your doctor before taking if you

- have asthma, diabetes, high cholesterol, high blood pressure, had a stroke, liver, heart, kidney or bowel problems
- are a smoker
- are pregnant

If symptoms do not get better or get worse or if you get new symptoms, talk to your doctor.

PIL:

1. Dosage:

Adults, the elderly and children over 12 years:

- This medicine is for short-term use only.
- Take the lowest dose for the shortest time necessary.
- Do not take 'X' for longer than 10 days.

If you do not get better, or get worse, talk to your doctor. They will tell you if it is safe to carry on taking the medicine.

2. Female fertility:

X belongs to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking the medicine. It is unlikely that if you only take X occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant talk to your doctor before taking this medicine.

3. Low dose aspirin

Do not take if you are taking more than 75mg of aspirin a day. If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take [PRODUCT].

4. Gastrointestinal side effects:

If you get any of the following at any time during your treatment
STOP TAKING, and get medical help straight away:

- Pass blood in your stools or motions
- Pass black tarry stools or motions
- Vomit any blood or dark particles that look like coffee grounds

STOP TAKING and tell your doctor if you experience:

- Indigestion or heartburn

Pains in your stomach (abdomen) or other abnormal stomach problems

NICOTINE REPLACEMENT THERAPY

Conditions for GSL supply

Carton:
If you are pregnant, talk to your doctor, pharmacist or nurse before using this product (* except liquorice flavoured gums – see below)
Do not use if you are pregnant or breastfeeding. Liquorice should not be used

during pregnancy or during breastfeeding.
If you need any advice before starting to use this product, talk to your doctor, pharmacist or nurse.

Carton (boxed):
You are more likely to quit smoking when using this product with help from your pharmacist, doctor, a trained counsellor, or a support programme.

NIZATIDINE

For medicines available as P for over-the-counter supply:
This medicine may be taken for up to 14 days. If you need to take it for longer than 14 days or your symptoms come back stop taking the medicine and talk to your doctor.

NON-SEDATING ANTI HISTAMINES

Medicines which fall into the class of non-sedating antihistamines (cetirizine, loratadine, etc) are known to cause drowsiness in a small number of patients. They cannot therefore claim to be non-drowsy on the packaging and should additionally include the following cautionary advice on the label:

This medicine does not normally make you feel sleepy. However, everyone reacts differently. If you do feel sleepy do not drive or use tools or machines. Do not drink alcohol.

A similar statement should appear in the patient information leaflet.

OPIOIDS

FRONT OF PACK (OTC medicines)

- Can cause addiction
- Contains opioid
- For three days use only

FRONT OF PACK (POM medicines)

- Can cause addiction
- Contains opioid

These requirements are in addition to the normal statutory provisions and should be prominently displayed.

PIL

Section 3

There is a risk that you may become addicted to or dependent on these tablets (a need to keep taking the medicines). If you take these for a long time you can become used to the effects and you may need to take higher doses to control your pain.

You should not suddenly stop taking these tablets unless your doctor tells you to. If you want to stop taking you tablets, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects. If you suddenly stop taking these tablets you may get withdrawal symptoms such as

- **agitation,**
- **anxiety,**
- **palpitations,**
- **shaking or**
- **sweating**

OXETACAINE

For medicines available as P medicines for oral use:
If you need to use this medicine for longer than 28 days stop taking and talk to your doctor.

PARACETAMOL

Paracetamol warnings are set out in the legislation. They are referenced in regulations 258 and 260 of the Human Medicines Regulations 2012 (as amended and appear in Part 4 of Schedule 25 and Part 2 of Schedule 27 to those regulations. They must be used verbatim. They are stated here for completeness.

SCHEDULE 25
Packaging requirements: specific provisions
PART 4
Medicines containing paracetamol

14. If the product contains paracetamol, except where the name of the product includes the word "paracetamol" and appears on the outer and immediate packaging, the words "Contains paracetamol".
***15.** If the product contains paracetamol the words "Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor", which must appear adjacent to either the directions for use or the recommended dosage.*
***16.** If the product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words "Do not take anything else containing paracetamol while taking this medicine" and—*
(a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 16 of Schedule 27 (package leaflets), the words "Talk to a doctor at once if you take too much of this medicine, even if you feel well"; or
(b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words "Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage".
***17.** If the product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words "Do not give anything else containing paracetamol while giving this medicine" and—*

(a) if a package leaflet accompanying the product includes the words in quotation marks in paragraph 17 of Schedule 27 (package leaflets), the words "Talk to a doctor at once if your child takes too much of this medicine, even if they seem well"; or
(b) if no package leaflet accompanies the product or the package leaflet does not include those words, the words "Talk to a doctor at once if your child takes too much of this medicine, even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage".

***18.** If the product is required by this Part of this Schedule to show the words set out in paragraphs 14, 16 or 17, those words must appear in a prominent position.*

SCHEDULE 27
Package leaflets
PART 2
Paracetamol

***16.** If a medicinal product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words "Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage".*
***17.** If a medicinal product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words "Talk to a doctor at once if your child takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage".*

For medicines which are principally for children or are for parenteral use, the wording above should be amended to ensure it makes sense in the context of how the product is used. No other deviations are acceptable.

PARAFFIN-CONTAINING EMOLLIENTS AND OTHER TOPICALLY APPLIED MEDICINES

Labelling:

The following symbol and warning are required on both the outer and immediate packaging for packs of 30g (or 30ml) and over.

Additional guidance:

- The symbol and pictogram should be reproduced as shown with the symbol in yellow and the warning presented on an orange background. An emboldened border in black should be used to increase the prominence of the information presented. The text must be presented in lower case lettering.

- For smaller pack sizes (50g/50ml or less) the symbol and warning should be presented on one face of the outer packaging, on which no other information should be applied.

- For larger pack sizes, the symbol and warning should be given due prominence on the outer packaging with a minimum font size of 10pt used for the text, as shown in the example above.

- On immediate packaging, such as tube, container and bottle labels, the symbol and warning should be prominently positioned in the main field of view, using as large a font size as possible.

Warning flash:
In addition to the above symbol and warning, a "flash" should be added to the outer packaging, or the immediate packaging where no outer carton is provided, alerting patients and carers to the new safety information. The colour of the flash should be chosen to ensure due prominence. The flash should state "New safety information – see label". This flash should remain on the outer packaging for a period of 12 months.

PIL:
Section 2 of the Patient Information Leaflet under the "Warnings and precautions" subheading should be updated to include the following wording:

"Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it."

PENICILLIN

This only applies to combination products or those with a brand name where it is not immediately apparent that the product contains a penicillin. The following statement should be added to the front face or most obvious field of view for container labels and should be displayed prominently:

Contains penicillin

POTASSIUM CHLORIDE (Concentrated)

Carton
FRONT FACE:

For IV infusion after dilution

Dilute at least “w” times with suitable diluent. Mix thoroughly before slow intravenous infusion.
“X”g in “Y”ml
“Y”ml contains « z » millimores of potassium

K

TOP & SIDE

K Dilute before use

Ampoule
“X” g in “Y” ml
« Y » ml contains « Z » millimoles of potassium
Dilute before use

K

MAHs who have more than one strength of strong potassium chloride solution should ensure clear differentiation between the packs by the judicious use of colour.

RANITIDINE

For medicines available as P for over-the-counter supply:
This medicine may be taken for up to 14 days. If you need to take it for longer than 14 days or your symptoms come back stop taking the medicine and talk to your doctor.

For medicines available as GSL for over-the-counter supply:
This medicine may be taken for up to 6 days. If you need to take it for longer than 6 days stop taking the medicine and talk to your doctor.

RIVASTIGMINE

Because of its therapeutic use, patients and carers expect to receive a calendar pack presentation of this medicine.

LABEL
Blister foils should include days of the week and an indication of both a morning and evening dose.

RETINOIDS (ORAL)

Labelling:
A boxed warning should be added to the outer packaging for the oral retinoids acitretin, alitretinoin and isotretinoin as follows:

WARNING:

CAN SERIOUSLY HARM AN UNBORN BABY
Women must use effective contraception
Do not use if you are pregnant or think you may be pregnant

PIL:

The following boxed warning should be included in the PL for the oral retinoids acitretin, alitretinoin and isotretinoin, under the invented name:

WARNING:

CAN SERIOUSLY HARM AN UNBORN BABY
Women must use effective contraception
Do not use if you are pregnant or think you may be pregnant

▼Do not use if you are pregnant or you think you may be pregnant This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Section 2. What you need to know before you take <TRADENAME>
Do not take <TRADENAME>
- If you are pregnant or breast-feeding.
- If there is any chance you could become pregnant, you must follow the precautions under ”Pregnancy and prevention programme”, see section on ”Warnings and precautions”.

Pregnancy prevention programme
Women who are pregnant must not take <TRADENAME>

This medicine can seriously harm an unborn baby (the medicine is said to be ‘teratogenic’) – it can cause serious abnormalities of the unborn baby’s brain, face, ear, eye, heart and certain glands (thymus gland and parathyroid gland). It also makes a miscarriage more likely. This may happen even if <TRADENAME> is taken only for a short time during pregnancy.

- You must not take <TRADENAME> if you are pregnant or if you think you might be pregnant.
- You must not take <TRADENAME> if you are breastfeeding. The medicine is likely to pass into your milk and may harm your baby.

- You must not take <TRADENAME> if you could get pregnant during treatment.
- You must not get pregnant for one month after stopping this treatment because some medicine may still be left in your body.

for acitretin this last bullet point should be:

- You must not get pregnant for 3 years after stopping this treatment because some medicine may still be left in your body.

Women who could get pregnant are prescribed <TRADENAME> **under strict rules. This is because of the risk of serious harm to the unborn baby**

These are the rules:

- Your doctor must explain the risk of harm to the unborn baby - you must understand why you must not get pregnant and what you need to do to prevent getting pregnant.
- You must have talked about contraception (birth control) with your doctor. The doctor will give you information on how not to get pregnant. The doctor may send you to a specialist for contraception advice.
- Before you start treatment, your doctor will ask you to take a pregnancy test. The test must show that you are not pregnant when starting treatment with <TRADENAME>

Women must use effective contraception before, during and after taking <TRADENAME>

- You must agree to use at least one very reliable method of contraception (for example an intra uterine device or contraceptive implant) or, two effective methods that work in different ways (for example a hormonal contraceptive pill and a condom). Discuss with your doctor which methods would be suitable for you.
- You must use contraception for a month before taking <TRADENAME>, during treatment and for a month afterwards [for acitretin should be during 3 years]
- You must use contraception even if you do not have periods or you are not sexually active (unless your doctor decides this is not necessary).

Women must agree to pregnancy testing before, during and after taking <TRADENAME>

- You must agree to regular follow-up visits, ideally every month.
- You must agree to have regular pregnancy tests, ideally every month during treatment and, because some medicine may still be left in your body, 1 month after stopping <TRADENAME> (unless your doctor decides this is not necessary in your case). [for acitretin: ‘every 1 to 3 months for 3 years after stopping <TRADENAME> ’]
- You must agree to extra pregnancy tests if your doctor asks you.

- You must not get pregnant during treatment or for a month afterwards because some medicine may still be left in your body.

for acitretin this last bullet point should be:

- You must not get pregnant during treatment or for 3 years afterwards because some medicine may still be left in your body.

- Your doctor will discuss all these points with you, using a checklist and will ask you (or a parent/guardian) to sign it. This form confirms that you have been told about the risks and that you will follow the rules above.

If you get pregnant while taking <TRADENAME> , **stop taking the medicine straight away**, and contact your doctor. Your doctor may send you to a specialist for advice.

Also, if you become pregnant within one month [3 years for acitretin] after you stop taking <TRADENAME> , you should contact your doctor. Your doctor may send you to a specialist for advice.

Advice for men T

he levels of oral retinoid in the semen of men taking <TRADENAME> are too low to harm their partners' unborn baby. However, you must never share your medication with anyone.

Additional precautions
You should never give this medicinal product to another person. Please Take any unused to your pharmacist at the end of treatment.

You should not donate blood during treatment with this medicine and for 1 month [3 years for acitretin] after stopping <TRADENAME> because an unborn baby could be harmed if a pregnant patient receives your blood.

Pregnancy, breast-feeding and fertility
For more information on pregnancy and contraception, see section 2 "Pregnancy and prevention programme".

The following sentence should be included at the end of the package Leaflet (last sentence):

<*Detailed and updated information on this product is available by scanning the QR code included in the PIL with a smartphone.* The same information is also available on the following URL: *[URL to be included] <and the <NCA> website>>*

SEDATING ANTIHISTAMINES

For Pharmacy Only (P) medicines which contain sedating antihistamines unless these are for external use e.g. chlorpheniramine, diphenhydramine:

Warning: This medicine may make you feel sleepy. If this happens do not drive or use tools or machines. Do not drink alcohol.

SODIUM CROMGLICATE

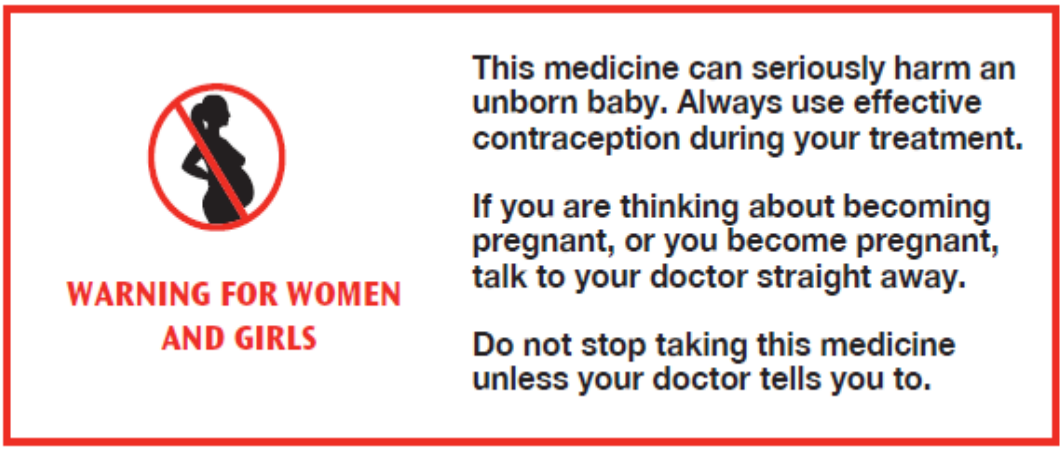
For medicines which are available over-the-counter for pharmacy only [P] supply:

Leaflet

Talk to your doctor or pharmacist if you have are not sure whether the child has allergic eyes. Also do this if you have any other questions about using these eye drops in a child.

SODIUM VALPROATE

Outer carton label warning and pictogram:



- The pictogram and warning should appear exactly as above, including the use of the red text and rectangle.
- The name and strength of the medicine should be positioned above the warning and pictogram with **no other information** appearing on the carton face.

Immediate packaging (blister foils, bottle, container, sachet and ampoule labels)

- Only the pictogram is required, without any of the warning text.
- On blister foils there should be multiple repeats of the pictogram accompanying the product name presented on the foil.

For medicines which are available over-the-counter for pharmacy only [P] supply:

SQUILL

The following statements should appear prominently on the label:
Do not take this medicine if you

- **Are an alcoholic**
- **Have breathing difficulties**
- **Have raised pressure in your head**
- **Have heart, liver or kidney problems**
- **Are allergic to anything in this medicine.**

SSRIs (selective serotonin reuptake inhibitors), Venlafaxine and Mirtazapine

A headlines section should be included as a matter of best practice

If you have any concerns about how you feel, or about this medication, it is important that you talk to your doctor - even if you feel anxious or worried about doing so.
You may find it helpful to tell a friend or relative that you are depressed or suffering from an anxiety disorder, and that you have been prescribed this medication; it might be useful to show them this leaflet.

- **< Product name > may not start to work immediately**. Some people taking antidepressants may feel worse before feeling better. Your doctor may ask to see you again a couple of weeks after you start treatment and then regularly until you start to feel well again. Tell your doctor if you do not start to feel better.
- **Some people who are depressed may think of harming or killing themself. If this happens you should see your doctor or go to a hospital straight away** – see in section 2 '*Thoughts of suicide and worsening of your depression or anxiety disorder*'
- **If you take too many capsules it is important to seek immediate medical attention, even if you feel well, because of the risk of serious side effects**
- **Do not stop taking <Product name > or change your dose without the advice of your doctor even if you feel better**. If you stop taking

<Product name > abruptly you may get withdrawal reactions – see in section 3 '*If you stop taking <Product name >*'

- **If you have heart problems such as fast or irregular heart rate or high blood pressure you should talk to your doctor before taking <Product name >** – see in section 2 '*Before you take <Product name >'*
- **Taking certain other medicines with <Product name > may cause problems. You should tell your doctor if you are taking any other medicines** – see in section 2 '*What you need to know before you take <Product name >*'
- **See your doctor without delay** if you feel restless and feel like you can't keep still, feel 'high' or very over-excited, have jerky muscle movements which you can't control. See section 4 – '*Possible side effects*' for other important information
- **If you are pregnant, or intend to become pregnant, or breast-feeding, you should talk to your doctor** – see in section 2 *'Pregnancy and breast-feeding*'

More information on all of these points is provided in the rest of this leaflet.

STEROIDS – all oral and parenteral

See entry for dexamethasone. Information should be amended to reflect the name of the active substance only.

THEOPHYLLINE

For P medicines and the product is for asthma or bronchial spasm.

Warning: Talk to your doctor before using this medicine

THIOMERSAL

For medicines which contain the preservative thiomersal there should be warning in the PIL as follows:

This medicine contains thiomersal as a preservative. It is possible that you or your child may have an allergic reaction to this.
Tell your doctor if you or your child have any allergies.

TIOCONAZOLE

See imidazoles

VINCA ALKALOIDS

The following statements should be prominently on the front face of the packaging **For intravenous use only.** **Fatal if given by other routes.**

5. DISPENSED MEDICINES & MEDICINES SUPPLIED BY A HEALTHCARE PROFESSIONAL

Although usually medicines will be supplied in a manufacturer's original pack to a patient the national regulatory framework requires the healthcare professional who supplies the medicine to include further labelling. These labelling provisions are set out in the Human Medicines Regulations 2012 and cover a number of scenarios which are explained below.

MEDICINES ON PRESCRIPTION

Medicines which are supplied by a pharmacist against a prescription issued by a *bone fide* prescriber should additionally have a dispensing label applied to the pack. The legal requirements for what should be included in the dispensing label are set out in Part 1 of Schedule 25 to the Human Medicines Regulations 2012. These are set out below:

1. Where the product is to be administered to a particular individual, the name of that individual.
2. The name and address of the person who sells or supplies the product.
3. The date on which the product is sold or supplied.
4. Unless paragraph 5 applies, such of the following particulars as the appropriate practitioner who prescribed the product may specify –
   (a) the name of the product or its common name
   (b) directions for use of the product
   (c) precautions for use of the product.
5. This paragraph applies if the pharmacist in the exercise of professional skill and judgement is of the opinion that the inclusion of one or more of the particulars mentioned in paragraph 4 is inappropriate.
6. Where paragraph 5 applies, the pharmacist may include such particulars, of the same kind as those mentioned in paragraph 4, as the pharmacist thinks appropriate.

MEDICINES SUPPLIED BY DOCTORS, DENTISTS, NURSES AND MIDWIVES

Medicines which are supplied by doctors, dentists, nurses and midwifes directly to the patient should be labelled according to Part 1 of Schedule 26 to the Human Medicines Regulations 2012. These are set out below:

1. Where the product is to be administered to a particular individual, the name of that individual.

2. The name and address of the person who sells or supplies the product.
3. The date on which the product is supplied.
4. Such of the following particulars as the appropriate practitioner who prescribed the product may specify –
   (a) the name of the product or its common name
   (b) directions for use of the product
   (c) precautions for use of the product.

PHARMACY EXCEPTIONS

Regulation 4 of the Human Medicines Regulations 2012 and section 10 of the Medicines Act 1968 allow pharmacists to supply medicines in circumstances which do not require the pharmacist to hold either a manufacturer's assembly licence or a marketing authorisation for the medicine in question. Nevertheless,such medicnes must be labelled according to the provisions set out in Part of Schedule 26 to the Human Medicines Regulations 2012. These are set out below:

5. Where the product is to be administered to a particular individual, the name of that individual.
6. The name and address of the person who sells or supplies the product.
7. The date on which the product is sold or supplied.
8. Where the product is prescribed by an appropriate practitioner, such of the following particulars as the appropriate practitioner who prescribed the product may specify, unless paragraph 9 applies –
   (a) the name of the product or its common name
   (b) directions for use of the product
   (c) precautions for use of the product.
9. This paragraph applies if the pharmacist in the exercise of professional skill and judgement is of the opinion that the inclusion of one or more of the particulars mentioned in paragraph 8 is inappropriate.
10. Where paragraph 9 applies, the pharmacist may include such particulars, of the same kind as those mentioned in paragraph 8, as the pharmacist thinks appropriate.

Where labels are applied to medicines under the provisions of Schedules 25 or 26 of the Human Medicines Regulations 2012, the following labelling statements should also appear:

- Keep out of the sight and reach of children
- If the product is for external use only and is an embrocation, liniment, lotion, cream, liquid antiseptic or other liquid preparation or gel:

  Use this medicine only on your skin.

MHRA

September 2019