

**MHRA**

151 Buckingham Palace Road  
Victoria  
London SW1W 9SZ  
United Kingdom

**Telephone**

+44 (0)20 3080 6039

**Email**

Abiodun.aderogba@mhra.gsi.gov.uk  
[mhra.gov.uk](http://mhra.gov.uk)

17 February 2014

Dear Sir/Madam

**CONSULTATION DOCUMENT: ARM 87; GALPHARM PERIOD PAIN RELIEF 250MG  
GASTRO-RESISTANT TABLETS**

**REQUEST TO RECLASSIFY A PRODUCT FROM P TO GSL**

I am writing to inform you that consultation document ARM 87 which includes the applicant's Reclassification Summary and Patient Information Leaflet, has been posted on the MHRA website today ([www.mhra.gov.uk](http://www.mhra.gov.uk)). The consultation seeks your views on the reclassification from P to GSL of Galpharm Period Pain Relief 250mg Gastro-Resistant Tablets.

You are invited to comment on the proposal and a form can be found on the website. Comments should be sent to me either by post to room 3-M, 151 Buckingham Palace Road, London SW1W 9SZ or by email ([reclassification@mhra.gsi.gov.uk](mailto:reclassification@mhra.gsi.gov.uk)) to arrive by **17 March 2014**. Contributions received after that date cannot be included in the exercise.

Please inform us of your email address if you wish to receive an electronic copy of all future consultations via email.

To help informed debate on the issues raised by this consultation exercise, and within the terms of the Freedom of Information Act, the Agency intends to make copies of comments received publicly available. Unless you state otherwise we will assume that you have no objections to your comments being publicly available on the Agency's website.

Yours faithfully

Abiodun Aderogba  
Self Medication Unit

**REPLY FORM: ARM 87; GALPHARM PERIOD PAIN RELIEF 250MG GASTRO-RESISTANT TABLETS**

To: Abiodun Aderogba

From: \_\_\_\_\_

MHRA

Room 3-M

151 Buckingham Palace Road

LONDON SW1W 9SZ

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**ALL RESPONDENTS MUST TICK ONE OF THE FOLLOWING BOXES**

- My reply may be made freely available ☐
- I wish my reply to remain confidential\* ☐
- I wish parts of my reply to remain confidential\* ☐

\*Please use the space below to explain why you feel the information in your reply should be treated as confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete

**Explanation regarding why your response should remain confidential**

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**Name:**

**Signature**

**Date:**

**Reclassification Summary**

**Galpharm Period Pain Relief 250mg Gastro-Resistant Tablets  
(Naproxen 250mg)**

**PL 16028/0144**

**P to GSL Variation Application**

**February 2014**

**Galpharm Healthcare Limited  
Upper Cliffe Road  
Dodworth  
Barnsley  
South Yorkshire  
S75 3SP**

## 1.2 RECLASSIFICATION SUMMARY

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### 1. Applicant Details

**Name of the applicant:**

Galpharm Healthcare Limited

### 2. Product Details

**Name:**

Galpharm Period Pain Relief 250mg Gastro-Resistant Tablets - PL 16028/0144

**Active:**

Naproxen, 250mg

**Indications:**

Indicated for the treatment of primary dysmenorrhoea in women aged 15 to 50 years.

**Current Dosage including age limits:**

For oral administration.

To be taken preferably with or after food swallowed whole with water.

Adolescents (post puberty) and adult females between the ages of 15 and 50:

On the first day 2 tablets (500 mg) should be taken initially and then one tablet (250 mg) after 6 to 8 hours if needed.

On the second and third day, if needed, one tablet (250mg) should be taken every 6 to 8 hours. Not more than 3 tablets to be taken per day. The maximum duration of continuous treatment in any one cycle (period) is 3 days.

**Pack size:**

Current	3, 6, 8 or 9 Tablets	Pharmacy (P)
Proposed	3, 6, 8 or 9 Tablets	General Sales List (GSL)

### 3. Rationale for the Reclassification

In February 2008, Naproxen 250mg Gastro-Resistant Tablets were reclassified from a prescription medicine to a non-prescription medicine. The non-prescription status was restricted to Pharmacy only supply and small packs sufficient to treat period pain lasting no longer than 3 days. There is a long history of women using pharmacy and General Sale medicines to safely and effectively relieve the symptoms of period pain. General sale supply offers women greater convenience and speed of access to effective treatment. Non-prescription naproxen has proven to be very popular with period pain sufferers and very well tolerated with a reasonable safety profile well within that of other general sale medicines. The applicant therefore believes that there is now sufficient evidence to show that supply of naproxen for the relief of period pain as a general sale medicine is appropriate and in the interest of period pain sufferers.

Dysmenorrhoea or period pain is a common, chronic, recurring and debilitating condition which affects 50-90% of adolescent females and young women. A significant number (>10%) of sufferers will experience interference with everyday life; in some cases leading to absence from work and educational settings, and also interfering with sport, socialising and family life. Primary dysmenorrhoea typically starts six to twelve months after the menarche. The average age of menarche in the UK is slightly over 12 years of age.

For many years women have managed their period pain using OTC (pharmacy and GSL) medicines. These include aspirin, paracetamol and ibuprofen as well as combination analgesics which may contain low levels of codeine. There are many such OTC analgesics which are licensed for a range of short term self limiting painful conditions such as headache, toothache, backache and flu including dysmenorrhoea.

Dysmenorrhoea responds well to treatment with NSAIDs. The pharmacological basis of this is thought to be because prostaglandins play a role in mediating the smooth muscle contractility of the womb. Women with dysmenorrhoea have been shown to have high levels of prostaglandins.

Ibuprofen is currently the only NSAID available GSL and licensed for the relief of dysmenorrhoea. Naproxen would be a valuable alternative.

### **Hazard to Health**

The safety data now available from the Pharmacy supply of naproxen show that as expected, naproxen is very well tolerated when used to relieve the painful symptoms of period pain. All spontaneously reported adverse events were minor and previously known. The hazard to health, risk of misuse and the need for special precautions in handling a GSL medicine are small when compared with the extra convenience to the purchaser.

### **Risk of Misuse**

There is no evidence that naproxen has been used incorrectly as a non-prescription medicine. Naproxen is not a drug of abuse and has a wide safety margin in accidental or intentional overdose. The product labeling and limited pack size (not more than 9 tablets) has also helped to reduce the possibility of incorrect use.

### **Special Precautions in Handling**

The non-prescription experience of supplying naproxen as a pharmacy medicine and the established GSL status of period pain suggest that there no special precautions are needed.

### **Convenience to the Purchaser**

The current Pharmacy pack of 9 tablets provides treatment for only one cycle, i.e. women are encouraged to only buy sufficient medication to treat one period at a time. Typical sufferers will therefore have to repeat purchase monthly.

Extending naproxen availability to GSL provides considerable convenience for the patient, particularly if a pharmacy is not locally available or open.

**Current Role of the Pharmacist in the supply of medicines for the relief of period pain including naproxen, and the role of labelling for GSL medicines indicated for the relief of period pain<sup>1</sup> :**

**Summary:** At present, naproxen is only available under the supervision of a pharmacist. Given that women currently self-medicate without the intervention of a pharmacist using a number different medications currently available through the GSL route of sale, removing the pharmacist from the process would not be expected to have an adverse effect on the safe supply of this medicine. The dispensing of many 'Pharmacy-only' medicines is often performed by a Pharmacy Assistant under the supervision of, rather than directly by, the responsible Pharmacist and thus the potential for identifying more serious related conditions may be limited by this. It is far more likely to be the patient themselves, having a knowledge of their own condition, who will prompt an identification of the symptoms in discussion with the Pharmacist, thus the role being one of confirming that a patient should be referred to a physician. As a result it is considered that the information provided on the outer packaging and patient information leaflet will be much more critical than the presence (or otherwise) of a Pharmacist in identifying more serious underlying conditions.

**How the pharmacist currently:**

- 1. Obtains information to identify any symptoms that may require referral;**
- 2. Selects possible, appropriate and effective treatment;**
- 3. Provides advice on the safe use of the selected treatment.**

When asked by a woman for advice the pharmacist or chemist counter assistance should be able to take the patient through the medicines information leaflet to determine whether or not the analgesic is suitable and whether the woman is suffering from any of the GP referral criteria:

The approved labelling of current and as well as proposed Pharmacy and GSL period pain medicines should be improved by addressing the following points:

- When did the period pain start?
  - Was the initial onset of symptoms related to the menarche? If the pain started after several years of painless periods or when the woman is over 30 years of age then she should be referred to her GP by the products approved labelling.
- The timing of pain in relation to the menstrual cycle.
  - If the pain precedes the onset of flow by more than a day or two then the labelling should refer the woman to her GP.
- If the pain is associated with dyspareunia (pain during sexual intercourse), vaginal discharge, menorrhagia, intermenstrual bleeding, and postcoital bleeding, then the labelling should refer the woman to her GP.
- If the period pain continues to significantly disrupting the woman's social, family and work life despite having tried OTC NSAIDs, paracetamol or complementary remedies, then the labelling should refer the woman to her GP.

Pelvic examinations are not considered necessary for women whose period pain responds adequately to analgesics and do not have any of the healthcare professional referral criteria mentioned above.

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<sup>1</sup> Expert Opinion on the current management of period pain (Primary Dysmenorrhoea) by women themselves and pharmacy staff using GSL and Pharmacy medicines. Cooke D and Eggleston R. August 2012.

**The risk-minimisation measures necessary to mitigate these risks in the GSL setting.**

Period pain is a common condition and most cases are safely self-treated using simple analgesic obtained from a general sales outlet or pharmacy. The labelling of these medicines should make it clear that in the case of severe period pain they should visit a healthcare professional (HCP) for advice and possible referral to make sure that no underlying medical condition is causing the pain.

Period pain typically starts when bleeding begins, although it can start a day or two days before the period starts. The pain normally lasts for one or two days and is worse during the heaviest flow. Medicine labelling should also direct women to seek HCP advised if their period is unusually painful in terms of intensity or duration. The symptoms of period pain tend to improve with age and following child birth.

Secondary Dysmenorrhoea is very often associated with:

- Irregular periods
- Bleeding in between periods
- Thick or foul-smelling vaginal discharge
- Pain during sex
- Fever
- Being over the age of 30 and experiencing period pain for the first time
- Changes in the normal pattern of period frequency, pain, duration or flow

Labelling of medicines indicated for the relief of period pain must make it clear that those women experiencing these symptoms should seek HCP advice. These can be considered the “red flag” or General Practitioner (GP) referral criteria.

A review of currently approved pharmacy and GSL labelling for analgesics licensed for the relief of period pain has highlighted some shortcomings in their labelling with regard to these “red flag” or HCP referral criteria. Not all medicines for period pain mention these HCP referral criteria. It is recommended that the labelling proposed for GSL naproxen include these HCP referral criteria. This should improve awareness amongst women and HCP about the importance of the above referral criteria in quickly detecting and managing secondary dysmenorrhoea. The adoption of such labelling by other prescription and non-prescription medicines intended for the treatment of period pain should be encouraged.

Failure to respond to one analgesic without the presence of these HCP referral criteria is not in itself a referral criterion since many women respond differently to different analgesics. However, failure to respond to a number of non-prescription analgesics or complementary therapies should be considered as HCP criteria.

**Identifying symptoms for referral:**

Adequate instruction is provided within the package labelling to alert women to the possibility that period pain can indicate an underlying condition that requires medical intervention. An itemised checklist has been included within the patient leaflet to achieve this.

The labelling of all medicines indicated for the relief of period pain should include the following risk-minimisation measures (healthcare professional referral criteria):

*Please see your healthcare professional for further advice if you notice any of the following with regards to your periods:*

- *Your periods are irregular*
- *Your period is unusually painful*
- *You have bleeding in between your periods*
- *You have a thick or foul-smelling vaginal discharge*
- *You have pain during or just after sex*
- *You have a fever*
- *You are over 20 years of age and this is the first time you are experiencing period pain*
- *You have noticed any changes in the normal pattern of your periods such as the intensity and duration of the pain or changes in the volume or duration of the blood flow*
- *Your period pain has not responded adequately to more than one kind of pain killer.*

### Support for reclassification

This is a company application with support from an independent expert.

### Specific GSL requirements

Conditions for GSL supply
Product will be POM unless the following conditions are met:  For internal use, in the form of enteric coated tablets  For the treatment of primary dysmenorrhoea in women aged between 15 and 50 years.*  Maximum strength: 250mg  Maximum dose: 500mg  Maximum daily dose: 750mg  Maximum duration of treatment: 3 days  Maximum pack size: 9 tablets  <b>*Note:</b> There are no changes proposed to the indications and posology and will be retained as current (refer section 2 for indication and dosage details).

The label will include:

Read the enclosed leaflet before taking this product.

**Do not take if you:**

- have or have ever had a stomach ulcer, perforation or gastrointestinal bleeding
- are allergic to naproxen or any other ingredient of the product, aspirin, ibuprofen or other related painkillers
- are taking other NSAID painkillers (aspirin, ibuprofen, diclofenac)
- have or have had kidney, liver or heart problems
- take any of the following medicines: Anticoagulants (eg. warfarin), Diuretics (water tablets), Lithium (for depression, bipolar, mania), Methotrexate (for cancer and other illnesses), Zidovudine (for HIV/AIDS), Ciclosporin or Tacrolimus (used after organ transplants).
- Are breast feeding, or there is a chance you may be pregnant.

**Speak to a pharmacist or your doctor before taking this product if**

- you have asthma or bowel problems

If symptoms persist or worsen, consult your doctor.

#### 4. Safety Profile

Non-prescription naproxen has proven to be well tolerated. Spontaneously reported adverse events have all been non-serious and previously known.

The safety of NSAIDs and the risk factors for NSAID-induced adverse events, particularly on the gastrointestinal tract and cardiovascular system have been the subject of many studies and reviews. The safety review which accompanied ARM41 in 2007 to reclassify naproxen as a pharmacy medicine adequately addressed these concerns for the use of naproxen in the context of short term use in healthy young women with period pain. The applicant has reviewed subsequent data and the overall risk-benefit of naproxen remains favorable when it is used in accordance with the product information as a pharmacy medicine and would also be so as a GSL medicine.

Patient Information Leaflet

## Galpharm Period Pain Relief

### 250 mg Gastro-Resistant Tablets

(Naproxen)

This leaflet has important information about your medicine. Please read it carefully before you take these tablets.  
If you have any questions, please ask your doctor or pharmacist.

#### WHAT IS YOUR MEDICINE FOR?

These tablets contain 250 mg of naproxen. This medicine is used to treat period pain (also called menstrual pain or dysmenorrhoea).

- Naproxen belongs to a group of painkillers called Non-Steroidal Anti-Inflammatory Drugs (also called NSAIDs).
- Other medicines in this group include ibuprofen and aspirin.

#### WHO SHOULD TAKE THIS MEDICINE?

Only take this medicine if you are between 15 and 50 years old.  
Ask your doctor, pharmacist or nurse if you need more information.

#### THINGS TO KNOW BEFORE TAKING YOUR MEDICINE

##### Do not take this medicine if you:

- have or have ever had a stomach ulcer, perforation or gastrointestinal bleeding.
- are allergic to naproxen or any other ingredient of the product (look at the list in the 'What's in these tablets' section, at the end of the leaflet), aspirin, ibuprofen or other related painkillers. Allergic reactions can include wheezing, itchy runny nose, rashes or swelling of the skin.
- are taking other NSAID painkillers (e.g. aspirin, ibuprofen, diclofenac).
- have or have ever had kidney, liver or heart problems.
- are breast feeding, or there is a chance you may be pregnant.

##### Do not take this medicine unless your doctor said you can, if:

- You started to have period pain more than a year after your first period.
- You have had a previous stroke or think you might be at risk of stroke (for example if you have high blood pressure, diabetes, high cholesterol or are a smoker).

- You have a blood clotting problem.
- You have asthma or any allergic illness which makes it hard to breathe.
- You have a stomach disorder such as ulcerative colitis or Crohn's disease.

Women who use an intrauterine device (IUD) as a contraceptive should consult with a doctor if they experience period pain.

You should speak to your doctor or a pharmacist if you are over 20 years of age and this is the first time that you have suffered from period pain.

Medicines containing naproxen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose (3 tablets a day) or duration of treatment (3 days) for any naproxen containing product.

##### Important information about some of the ingredients of this medicine

- This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**Driving and using machines:** These tablets may make you dizzy, sleepy or cause vertigo, loss of concentration, difficulty sleeping, depression or visual problems. Do not drive or use machines if this happens to you.

**Do not take this medicine if you have taken it for your last two periods and have not experienced relief of your symptoms.**

**Talk to your doctor before using this medicine if you have experienced any of the following symptoms:**

- Your periods are irregular.
- Your period is unusually painful.
- Your period pain becomes gradually worse during each subsequent period.
- The pain begins more than one day before the onset of bleeding.
- The pain is severe over the whole time of your period.
- Your period is more heavy than normal.
- Your period is longer than normal.
- Your period is later than normal.
- You experience bleeding between your periods.
- You have a thick or foul-smelling vaginal discharge.
- You experience pain during or just after, sexual intercourse.
- You have a fever.

- You started to have period pain more than a year after your first period.
- You have noticed any changes in the normal pattern of your periods such as the intensity or duration of the pain, or changes in the volume and duration of blood flow.
- Your period pain has not responded adequately to more than one kind of pain killer.

**Talk to your doctor or pharmacist first, if you are taking any of these other medicines:**

- Anticoagulants (e.g. warfarin)
- Diuretics (water tablets)
- Lithium (for depression, bipolar, mania)
- Methotrexate (for cancer and other illnesses)
- Zidovudine (for HIV/AIDS)
- Ciclosporin or Tacrolimus (used after organ transplants)
- Steroids (also called corticosteroids) - like prednisolone.
- Quinolone antibiotics (ciprofloxacin, norfloxacin or levofloxacin) or sulphonamides (like co-trimoxazole).
- Probenecid – a medicine for gout.
- Medicines for high blood pressure (anti-hypertensives).
- Medicines for your heart (digoxin or glycosides).
- Phenytoin - a medicine for epilepsy.
- Mifepristone to terminate a pregnancy in the last 8 - 12 days.
- Antidepressants of the serotonin re-uptake inhibitor (SSRI) type like fluoxetine.

#### HOW TO TAKE THIS MEDICINE

##### First day:

- As soon as the pain starts, take **two** tablets.
- Then after 6 to 8 hours, take **one** more tablet that day, if you need it.

##### Second day:

- Take **one** tablet every 6 to 8 hours if needed.

##### Third day:

- Take **one** tablet every 6 to 8 hours if needed.

**Do not take more than 3 tablets each day.**

**Always take the lowest effective dose for you. Do not take more than the recommended dose of up to three tablets in a day. Do not take for longer than three days in any one month (menstrual cycle).**

Please turn over ➡

##### Taking the tablets:

- Swallow the tablets whole with a drink of water. Do not chew or crush them.
- **Take the tablets with or after food.**
- Only take the tablets for as long as you need them for the period pain. You may not need to take the tablets all the time for all 3 days. If you still have pain after 3 days of treatment, talk to your doctor. Do not take the tablets for more than 3 days in any one period (cycle).
- If you see a doctor, pharmacist or nurse or go into hospital, tell them you are taking this medicine.
- Overdose: If you (or someone else) takes too many tablets, go to the nearest hospital casualty department or your doctor straight away.

#### SIDE EFFECTS THAT MIGHT HAPPEN WHILE TAKING YOUR MEDICINE

Like all medicines, these tablets can cause side effects, although not everybody gets them. If you have any side effect, you should seek advice from your doctor, pharmacist or other healthcare professional. In addition, you can help to make sure that medicines remain as safe as possible by reporting any side effects via the internet at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or fill in a paper form available from your local pharmacy. You may also contact Medical Information given in the contact details at the end of this leaflet.

**If any of the following happen to you, stop taking the tablets and tell a doctor, pharmacist or nurse immediately:**

- Allergic reactions like asthma, wheezing or difficulty breathing. This may be severe.
- Severe blisters and bleeding of the skin, nose and mouth (Stevens-Johnson syndrome).
- Skin problems including rashes, itching, nettle rash or a bruise like rash. There may also be blistering and flaking of the skin.
- Swelling of the face, lips, tongue and throat (causing difficulty swallowing or breathing).
- Sickness or being sick (possibly with blood), diarrhoea (sometimes with blood and mucus), dark "tarry" stools.
- Stomach pain, indigestion, stomach ulcers and bleeding in the stomach.
- Worsening of stomach problems (ulcerative colitis or Crohn's disease).
- Sore mouth or unusual painful mouth ulcers.
- Blood in the urine, more or less urine than normal or cloudy urine. Pain around the kidneys (lower side of your back).

- Jaundice (yellowing of the skin or whites of the eyes), and/or pale coloured stools and dark urine.
- Fits (convulsions), altered vision, pins-and-needles or numbness, confusion, hallucinations, dizziness and vertigo, hearing problems.

**If you have any of the following while taking this medicine, stop taking it and tell your doctor:**

- Swelling of the blood vessels and a build up of fluid which may cause swollen ankles.
- Kidney or liver problems: these will show up in blood or water tests.
- Nervous system: headaches, depression, insomnia, ringing in the ears, tiredness, drowsiness, inability to concentrate, mental slowing, a general feeling of being unwell or fever with a dislike of light.
- Blood problems – these may cause unusual tiredness or weakness, unusual bleeding or unexplained bruising, fever or chills, sore throat or ulcers in your throat.
- Sensitivity of the skin to light.
- Hair loss (alopecia).
- Flatulence or constipation.
- Your period pain becomes gradually worse during each subsequent period.
- The pain begins more than one day before the onset of bleeding.
- The pain is severe over the whole time of the menstrual period.

##### Other side effects

- High blood pressure and heart failure have been reported with NSAID use.
- Medicines which contain NSAIDs such as naproxen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.
- NSAIDs have been associated with aseptic meningitis which can include symptoms of headache, stiff neck, disorientation, fever and sensitivity to light in people with auto-immune disorders.
- Not everyone will respond to NSAIDs. If this medicine does not work for you, talk to your pharmacist or doctor.

If you experience any other symptoms or have concerns about your medicine, talk to your doctor.

**Adrenal function tests:** The tablets may interfere with these tests – check with your doctor before the test.

#### HOW TO STORE YOUR TABLETS

- Do not use this medicine after the use-by date
- Keep these tablets in their original packaging and do not store above 25°C
- Store your medicine in a safe place, out of the sight and reach of children
- This medicine is for you ONLY, do not give it to anyone else
- Return all unused medicines to your pharmacist for safe disposal

#### WHAT IS IN THESE TABLETS?

Each white round coated tablet contains 250 mg of naproxen, which is the active medicine. The tablets come in a box of 9 tablets. The tablet is gastro-resistant (also known as enteric coated). This means that it is covered with a coating which stops the tablet dissolving in the stomach, so that the naproxen is released further down in your gut.

The tablets also have inactive contents: lactose monohydrate, maize starch, polyvidone, sodium starch glycolate (type A) and magnesium stearate (E572). Also, the coating contains colloidal silicon dioxide, polyvinyl acetate phthalate, polyethylene glycol, purified stearic acid (E570), hydroxypropyl methylcellulose (E464), sodium alginate (E401), sodium bicarbonate (E500), purified talc (E553(b)), triethyl citrate, the colour titanium dioxide (E171) and black printing ink (containing shellac (E904), soya lecithin (E322), antifoam agent and black iron oxide (E172)).

The marketing authorisation holder is Galpharm Healthcare Limited, South Yorkshire S75 3SP. The company responsible for manufacture is TEVA UK Limited, Eastbourne, BN22 9AG, England.

#### REMEMBER




This leaflet does not contain all the information about these tablets.  
Please ask your doctor, nurse or pharmacist if you have any questions.

Text revised: September 2013.

Contact details:  
Medical Information, Galpharm International Ltd (Perrigo),  
Dodworth Business Park, Barnsley, South Yorkshire, S75 3SP.  
Tel 01226779911, Fx 01226704957, Txt 07899912051,  
email: [pharmacist@perrigouk.com](mailto:pharmacist@perrigouk.com)

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 <p>Perrigo is the trading name of <b>Galpharm International Limited</b>, Dodworth Business Park, Barnsley, South Yorkshire S75 3SP TEL: +44 (0) 1226 779911   FAX: +44 (0) 1226 779168 <b>Wratton Laboratories Limited</b>, Wratton, Braintree, North Devon EX33 2DL TEL: +44 (0) 1271 615815   FAX: +44 (0) 1271 618997 <a href="http://www.perrigouk.com">www.perrigouk.com</a></p>	Product Description Galpharm Period Pain Relief 250mg Gastro Resistant Tablets			Colour Swatches		
	Component	Leaflet	HUB No.	3218	 <b>Black</b>	
	Component No.	4000357	Supplier	TEVA UK Ltd		
	Date	12/09/13	Supplier Code	TBC		
	Version	10	Cutter Profile	130x323mm	Additional Swatches	
	Amended By	DH	Pharmacode	TBC	 <b>Cutter</b>	

## CONSULTATION LIST: ARM 87

Advertising Standards Authority  
Advisory Committee on Misuse of Drugs  
Arthritis Care  
Association of Anaesthetists of GB and Ireland  
Association of British Cardiac Nurses  
Association of Pharmaceutical Importers  
Association of the British Pharmaceutical Industry  
Asthma and Allergy Research  
AstraZeneca UK Ltd  
Boots Pharmacists Association  
British Association for Nursing in Cardiovascular Care  
British Association of Dermatologists  
British Association of European Pharmaceutical Distributor  
British Association of Pharmaceutical Physicians  
British Association of Pharmaceutical Wholesalers  
British Generic Manufacturers Association  
British Heart Foundation  
British International Doctors Association  
British Medical Association  
British Medical Association (Wales)  
British Retail Consortium  
British Society for Allergy & Clinical Immunology  
British Society of Gastroenterology  
Central Medical Advisory Committee  
Chemist & Druggist  
Committee for Practitioners  
Community Pharmacy Magazine  
Company Chemists Association  
Department of Agriculture  
Department of Health, Social Services and Public Safety, Northern Ireland  
Dispensing Doctors' Association  
Doctor magazine  
General Medical Council  
General Practitioners Association (NI)  
Health Service Commissioner  
Imperial Cancer Research Fund  
Independent Healthcare Forum  
Medical Protection Society Ltd  
Medical Women's Federation  
National AIDS Trust  
National Back pain Association

National Federation of retail Newsagents  
National Pharmaceutical Association  
Neurological Alliance  
Northern Ireland Consumer Council  
Nursing and Midwifery Council  
Ophthalmic Group Committee  
OTC Bulletin  
Paediatric Chief Pharmacists Group  
Patients Association  
Pharmacy and Medicines Division (Scotland)  
PSNC  
Royal College of General Practitioners  
Royal College of Nursing  
Royal College of Pathologists  
Royal College of Physicians  
Royal College of Physicians (Edinburgh)  
Royal College of Physicians and Surgeons of Glasgow  
Royal College of Psychiatrists  
Royal College of Surgeons (Edinburgh)  
Royal College of Surgeons (England)  
Royal Pharmaceutical Society  
Scottish Executive  
Scottish General Practitioners Committee  
Scottish Wholesale Druggists Association  
Surgical Dressing Manufacturers Association  
Terrence Higgins Trust  
The Association of Independent Multiple Pharmacies  
The Royal College of Radiologists  
UK Homeopathic Medical Association  
UK Inter-professional Group  
UKCPA  
WHICH  
Women in medicine