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14 January 2015

Dear Sir/Madam

CONSULTATION DOCUMENT: ARM 89; SOLEVE SUNBURN RELIEF CUTANEOUS EMULSION

REQUEST TO RECLASSIFY A MEDICINAL PRODUCT FROM PHARMACY (P) TO GENERAL SALE LIST (GSL)

This consultation seeks your views on the reclassification from P to GSL of Soleve Sunburn Relief Cutaneous Emulsion. Consultation document ARM 89 which includes the public reclassification report, product information and response document has been posted on GOV.UK, the new home on the web for all consultations from central government.

You are invited to comment on the proposal and the response form can be found within the consultation document. Comments should be sent to me either by post to Floor 4-O, 151 Buckingham Palace Road, London SW1W 9SZ or by email (reclassification@mhra.gsi.gov.uk) to arrive by **4 February 2015.** Contributions received after that date cannot be included in the exercise.

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

Soleve Sunburn Relief Cutaneous Emulsion: Reclassification from Pharmacy to General Sale List

Public reclassification report for ARM 89:

Product name: Soleve Sunburn Relief Cutaneous Emulsion
Active substances: Ibuprofen, isopropyl myristate
Licence holder: Diomed Developments Limited
Route of sale/supply: Current – through Pharmacies (P); Proposed – General Sale List (GSL)
Indication: For the relief of pain associated with mild to moderate sunburn in adults and children aged over 12 years**.**
Marketing Authorisation Number: PL 00173/0167
Consultation is open from: 14 January 2015 – 4 February 2015
Contact: reclassification@mhra.gsi.gov.uk

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency responsible for regulating medicines and medical devices. We continually review the safety of medicines and vaccines in the UK, and inform healthcare professionals and the public of the latest updates through several means, including public reclassification reports. Suspected side-effects to any drug or vaccine can be reported to the MHRA by both healthcare professionals and members of the public via the Yellow Card Scheme (http://www.mhra.gov.uk/yellowcard)

1. Background on reclassification

The MHRA assesses applications to reclassify medicines. Depending on the nature of the proposed classification, the MHRA might also take advice from its committees of external experts, run a public consultation, and consult a group ('stakeholder group') comprising health professionals and representatives of people affected by the classification change.

A company or organisation applying for a medicine to be classified either as pharmacy medicine or a general sale medicine first needs to assemble the evidence to show that the medicine is likely to be used appropriately and with relatively little danger to the public.

A proposal to change a medicine's classification needs to be supported by good clinical evidence that focusses on the risk to the public on changing the classification. Evidence on the medicine's potential for abuse[1] or misuse needs to be considered. The evidence may comprise clinical studies, extensive clinical use indicating acceptable level of side effects, advice of experts, views of relevant health professionals and their professional bodies, as well as the views of relevant public associations and individuals with an interest in the medicine under consideration. The evidence needs to demonstrate that the risk to the public will be adequately managed.

Explanations of terms used within this document can be found if required in the MHRA glossary at www.mhra.gov.uk/SearchHelp/Glossary/index.htm.

2. Introduction

Soleve Sunburn Relief Cutaneous Emulsion is a preparation to be applied to the skin for the relief of pain associated with mild to moderate sunburn in adults and children aged over 12 years. The licence-holder for Soleve Sunburn Relief Cutaneous Emulsion (Diomed Developments Limited) has applied to make this product available on the General Sale List. Soleve Sunburn Relief Cutaneous Emulsion is currently a Pharmacy medicine.

Commission on Human Medicines has advised that this product can be available as a General Sales List medicine. This report outlines the evidence that was reviewed which led to this decision. Please tell us your views by using the response form at the end of this document (Annex 1). The deadline for comments is **4 February 2015**.

The patient information leaflet and label are provided in Annex 2 and 3.

3. Background

Soleve Sunburn Relief was first authorised as Ibusol Lotion as a Prescription Only Medicine in September 2002. The product was not marketed as a Prescription Only Medicine because people rarely consult their doctor for mild to moderate sunburn.

In 2009, an application was granted for a Prescription Only Medicine to Pharmacy reclassification application for the relief of pain associated with mild to moderate sunburn in adults and children aged over 12 years.

This is the first Pharmacy to General Sales List application for this product.

3.1 Legal status of ibuprofen

Ibuprofen is a Prescription Only Medicine. However, it is available without prescription as a gel or spray to be applied to the skin ('topical') to treat backache, rheumatic pain, and muscular aches, pains or swellings such as strains, sprains and sports injuries. It is also available without a prescription as a tablet and as a liquid to treat painful conditions such as headache, dental pain, period pain, rheumatic and muscular pain, backache, and the symptoms of colds and flu.

3.2 Legal status of isopropyl myristate

Isopropyl myristate is a General Sales List medicine. Isopropyl myristate is available in many medical and cosmetic products such as moisturisers.

3.3 Topical treatment of sunburn

There are many cosmetic ‘after-sun’ products on the market. There are also several medicines licensed for the topical treatment of sunburn with a legal status of Pharmacy or General Sales List. These contain moisturisers, antiseptics, and medicines that numb areas of the body or stop itchiness. Most list sunburn as one of several skin conditions for which the product may be used. There are currently no other painkilling medicines licensed for sunburn.

4. Proposed terms of reclassification

The application proposes the following conditions for General Sales List supply of Soleve. These terms are the same as those currently authorised for Pharmacy supply. There are no proposed changes to the product itself or any of the information supplied with the product (e.g. package leaflet).

- For topical use
- Strength: 1% w/w ibuprofen and 10% w/w isopropyl myristate
- Indication: for the relief of pain associated with mild to moderate sunburn
- Population: adults and children over the age of 12 years
- Maximum dose: 120mg ibuprofen
- Maximum daily dose: 1000mg ibuprofen
- Maximum pack size: 200ml (containing 2g ibuprofen).

5. General Sales List criterion

Under the provisions of The Human Medicines Regulations 2012, regulation 62(5), General Sales List is appropriate for medicines which can, with reasonable safety, be sold or supplied by someone other than a pharmacist. The term “with reasonable safety” has been defined as: “where the hazard to health, the risk of misuse, or the need to take special precautions in handling is small and where wider sale would be a convenience to the purchaser."

6. Assessment of suitability for General Sales List availability

The MHRA assessed the application against the General Sales List criterion, stated in Section (5):

6.1 Hazard to health

Soleve has been marketed as a Pharmacy product from end of 2011 and it is estimated about 20,000 units have been sold since then. Each unit represents one treatment ‘course’ (the bottle size is 100 ml. Although the maximum recommended dose is 100 ml daily for 2 to 3 days, in practice the dose administered is likely to be much less than this because the product spreads easily and so ‘goes a long way’).

Between the end of 2011 and the end of 2014, only one spontaneous report has been received. This report related to drug ineffectiveness with no associated side effects. Due to the low Pharmacy sales and the small amount of data from clinical practice for this product, it is difficult to accurately assess the likely incidence and severity of side effects. As a result of this the licence-holder will be required to supply periodic safety update reports at the same frequency as that stated for newly-licensed products: 6-monthly for the first two years, annually for the subsequent two years; thereafter at 3-yearly intervals

The licence-holder provided data on the safety of other topical products containing ibuprofen. Side effects reported with other topical preparations of ibuprofen (5% and 10%) are mostly local site reactions. In addition, there have been reports of side effects affecting other parts of the body, including indigestion, stomach pain, bronchospasm, and kidney impairment associated with the use of the 5% and 10% gel preparations.

There are a number of “standard” risks for ibuprofen:

- allergic reactions
- use by people with stomach problems
- use by people with kidney problems
- use by people with asthma
- use in pregnancy and breastfeeding
- use with other non-steroidal anti-inflammatory drugs
- use in children under 12 years.

The standard risks are managed in other topical medicines containing ibuprofen by detailing them in the package leaflet as side effects, cautions, and contraindications. These details appear in the same way in the package leaflet for Soleve Sunburn Relief Cutaneous Emulsion.

6.2 Risk of misuse

The application has identified five risks for any sunburn treatment, irrespective of the active substance. These do not relate directly to the safety of Soleve but to the risks involved with treating sunburn:

- Misdiagnosis
- Misuse in severe sunburn
- Sunburn in very young children
- Potential confusion with sunblock
- Irresponsible behaviour in the sun

The assessment of each of these risks is outlined below.

6.2.1 Misdiagnosis

The application states that most people are familiar with sunburn, and are likely to have experienced it themselves at some time. Misdiagnosis of sunburn is considered unlikely because sunburn becomes apparent very soon after sun exposure. Some people may also experience heat rash reactions following sun exposure. However, it is unlikely that this would be confused with sunburn due to difference in the appearance and symptoms. It is considered very unlikely that people could confuse sunburn with a more serious skin condition such as cellulitis.

Soleve is only indicated for 'mild to moderate sunburn', which is described in the following way by NHS Direct: "mild to moderately sunburnt skin is red and sore. It is warm to the touch even after attempts to cool it with water or by moving into the shade". This definition is included in the proposed summary of product characteristic and package leaflet.

6.2.2 Misuse in severe sunburn

Mild to moderate sunburn and the symptoms of more serious sunburn are described in the package leaflet in user-friendly language, taken directly from NHS websites where applicable. The leaflet explains the symptoms of severe sunburn or heatstroke to make sure they are easily recognisable ("blistered skin, intense pain, intolerance of contact with clothing, fever, chills, feeling sick and extreme exhaustion or lack of energy"). The leaflet clearly instructs to get medical help quickly in such circumstances.

The leaflet also states that Soleve should not be used where a large proportion of the skin is red and sore from sunburn even if it is not blistered. If this happens, people are advised to get help from a doctor.

It is considered that people are able to diagnose mild to moderate sunburn correctly from the information available on the packaging and without the need for help from a pharmacist. The package leaflet makes it clear that medical attention is needed if their symptoms are severe.

6.2.3. Sunburn in very young children

Soleve is licensed for adults and children over 12 years old. The age restriction is stated on the labelling of the product and advises parents to get advice from a doctor or pharmacist if a child under 12 suffers from sunburn.

It is considered that there is sufficient warning on the packaging and leaflet, without the need for an intervention from a pharmacist to inform people that the product should not be used in young children.

6.2.4 Potential confusion with sunblock

The Soleve packaging states:

- *"Soleve is not a sunscreen or sunblock and cannot be used for this purpose. Do not expose the sunburnt areas to the sun until they are completely better."*
- *"Soleve is for short-term use to relieve sunburn and should not be used as a general aftersun lotion."*

Confusion with a sunblock is a risk not limited to Soleve: it exists for all sunburn relief products, whether medicines, cosmetics, or devices.

The confusion with sunblock is not considered to be a major concern and it is considered that the packaging can mitigate this risk sufficiently without the need for an intervention from a pharmacist

6.2.5 Irresponsible behaviour in the sun

It is possible that use of Soleve might encourage people to return to the sun sooner than they should (because they stop noticing the sunburn), or stay out in the sun longer than they should (because they can treat sunburn if it occurs). The proposed availability of Soleve on the General Sale List may lead people to purchase it before of sun exposure in case they get burnt. This could be interpreted as contradictory to advice regarding responsible behaviour in the sun, which recommends that people avoid getting burnt in the first place. It is not known whether people will alter their behaviour in the sun in response to the availability of this product.

However, it is considered that the label and leaflet warning statements provide enough opportunity to educate people that this is not a sunblock and reinforce the precautions to take when in the sun to avoid getting burnt.

6.3 Need for special precautions in handling

There are no special precautions required in handling this product.

6.4 Wider sale would be a convenience to the purchaser

There are already several topical treatments for sunburn available on the General Sale List and misdiagnosis is considered unlikely. Widening the choice to include a product which has a different mode of action to the currently available products would be beneficial to people with sunburn.

7. Risk Management Plan

The application contains a risks management plan that aims to foresee risks, and includes information on how these risks will be prevented or minimised.

The instructions about safe use of the product comprise prominent warning on the labelling and leaflet.

The routine pharmacovigilance practice measures in place by the company will continue to monitor use so that further measures can be taken to limit any identified incorrect use in the General Sales List setting. The company will be committed to providing periodic safety update reports at the same frequency as that stated for newly licensed products: 6-monthly for the first two years, annually for the subsequent two years; thereafter at 3-yearly intervals.

8. Advice from the Commission on Human Medicines

The Commission on Human Medicines advised that Soleve Sunburn Relief Cutaneous Emulsion is considered to be suitable for supply as a General Sales List medicine for the for the relief of pain associated with mild to moderate sunburn.

9. Consultation advice sought

Please tell us your views by using the response form in Annex 1. The deadline for comments is **4 February 2015**.

ANNEX 1

RESPONSE DOCUMENT FOR MHRA CONSULTATION ON SOLEVE SUNBURN RELIEF CUTANEOUS EMULSION PHARMACY TO GENERAL SALE LIST RECLASSIFICATION (ARM 89)

Your details

Name:
Position (if applicable):
Organisation (if applicable):
Email:

1. Do you consider that Soleve Sunburn Relief should be available as a General Sale List medicine?

Yes ☐ No ☐ Not sure ☐

Please provide any comments or evidence to support your response:

2. Do you have any specific comments on the leaflet or the label provided in the public reclassification report for Soleve Sunburn Relief?

3. Do you have any other comments on the reclassification?

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes ☐ Partially* ☐ No ☐

*If partially, please indicate which parts you wish to remain 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.

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gsi.gov.uk) to arrive by **4 February 2015.** Contributions received after that date cannot be included in the exercise.

PACKAGE LEAFLET: INFORMATION FOR THE USER

ANNEX 2

SOLEVE™ SUNBURN RELIEF

CUTANEOUS EMULSION

ibuprofen 1% w/w
isopropyl myristate 10% w/w

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Soleve carefully to get the best results from it. Keep this leaflet. You may need to read it again. Ask your pharmacist if you need more information or advice. You must contact a doctor if your symptoms worsen or do not improve after a few days. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT SOLEVE IS AND WHAT IT IS USED FOR

- Soleve is a lotion applied to mild to moderately sunburnt skin to relieve the pain of the sunburn and to moisturise the skin.
- Mild to moderately sunburnt skin is red and sore. It is warm to the touch even after attempts to cool it with water or by moving into the shade.
- **Soleve is not a sunscreen or sunblock and will not protect your skin from the sun.**
- Soleve is recommended for use by **adults, the elderly and children over the age of 12 years.**
- There are two types of **active ingredient** in this product:
  - **Ibuprofen** is one of a group of medicines known as Non-Steroidal Anti-Inflammatory Drug (NSAIDs). It works by relieving pain.
  - **Isopropyl myristate** is an emollient which soothes and moisturises your skin by trapping moisture in the skin.

2. BEFORE YOU USE SOLEVE

Do not use Soleve:

- if the **sunburn is severe.** Seek medical advice immediately if you have symptoms of severe sunburn including blistered skin, intense pain, intolerance of any contact with clothing, fever, chills, feeling sick and extreme exhaustion or lack of energy, seek medical advice;
- if a **large proportion of the body surface is involved.** As a general guide, seek medical advice immediately if more than one tenth (1/10) of a child's body surface (e.g. more than the equivalent area of the forehead, plus shoulders and tops of both arms), or if more than one fifth (1/5) of an adult's body surface (e.g. more than the equivalent area of both thighs and knees, plus shoulders and tops of both arms) has been burned.
- if you are **allergic (hypersensitive)** to ibuprofen, isopropyl myristate or any of the other ingredients of Soleve listed in Section 6;
- if you are **asthmatic**, or suffer from **rhinitis** (allergic runny nose) or **urticaria** (hives) **and** have ever had a bad reaction to aspirin, ibuprofen or other NSAIDs in the past;
- if you are **pregnant or breast-feeding;**
- on infected, diseased, broken or damaged skin **(this includes skin with sunburn blisters)**;
- **on children under 12 years** (parents should seek advice from a doctor or pharmacist if anyone under this age is sunburnt);

Before applying this product for the first time, make sure it is suitable for you to use.

Because Soleve is applied directly to the skin, there is less risk of the complications that sometimes occur when ibuprofen (or a similar anti-inflammatory painkiller) is taken by mouth. However, in rare cases you may be at more risk of complications:

- if you have a stomach ulcer (also called a peptic or gastric ulcer);
- if you have ever had kidney problems;
- if you have ever had asthma;
- if you have ever had a bad reaction to aspirin or ibuprofen taken by mouth.

If any of the previous warnings apply to you, only use this product on advice from your doctor or pharmacist.

Take special care when using this product.

- **Soleve is not a sunscreen or sunblock and will not protect your skin from the sun.**
- **Do not expose the sunburnt areas to the sun until they are completely better.**
- Soleve is for short-term use to relieve sunburn and should not be used as a general aftersun lotion.
- Use it only on the skin.
- Keep the lotion away from the eyes, nostrils and mouth.

Using other medicines

- Interaction between Soleve and blood pressure lowering drugs and anticoagulants (medicines that stop blood clotting) is possible, in theory, although very unlikely. If you would like more advice about this, speak to your doctor or pharmacist.
- Do not use Soleve lotion at the same time as any other medicines (including medicines obtained without prescription) containing ibuprofen, aspirin or any other NSAIDs.
- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including other medicines obtained without prescription.

Pregnancy and breast-feeding

You should not use Soleve if you are pregnant or breast-feeding.

Driving and using machinery

Using this product is not known to affect your ability to drive or use machinery.

3. HOW TO USE SOLEVE

To use the lotion (for adults, the elderly and children **over 12 years old**)**:**

- Use as soon as possible after the first sign of sunburn. Lightly apply the lotion to the affected areas and massage gently into the skin.
- Use the lotion at regular intervals, up to eight times a day, leaving **at least two hours between applications.**
- The lotion spreads very easily (a little goes a long way) and **you will not need to apply very much**. The amount needed depends on the area which is sunburnt, but as a very rough guide, an amount ranging from a 1 penny piece to a 2 penny piece will usually be sufficient.
- Do not apply more than 12 ml at a time, or more than 100 ml a day. As a guide, one and a half capfuls is approximately 12 ml.
- Wash hands after use, unless treating them.
- The lotion is designed to resist being washed off whilst swimming or bathing.
- Use the lotion for **a maximum of two to three days**, by which time your symptoms should have subsided.
- If your symptoms worsen, or continue for more than a few days, you should consult a doctor or pharmacist.
- Where Soleve is used on children, it should always be applied by an adult.

If the lotion comes into contact with broken skin or gets into the eyes, nostrils or mouth

- The product may cause irritation if it comes into contact with broken skin or gets into the eyes, nostrils or mouth. If this happens, rinse the

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affected areas with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists, tell your doctor or pharmacist.

If the lotion is accidentally swallowed

- If the lotion is swallowed by a baby or young child, contact a doctor or hospital straight away.
- For adults, if the lotion is swallowed and you experience any symptoms such as headache, vomiting, drowsiness or dizziness, contact a doctor or hospital straight away.

If you forget to use this product

Do not apply a double amount of Soleve to make up for a forgotten application. Apply it when you remember, then allow at least 2 hours before the next application. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Soleve can cause side effects, although not everybody gets them. If any side effect gets worse, or if you notice any not listed in this leaflet, please tell your doctor or pharmacist. Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.yellowcard.gov.uk or you can call Freephone 0808 100 3352 (available between 10am - 2pm Monday to Friday) or fill in a paper form available from your local pharmacy.

Occasionally, because sunburnt skin is tender, the initial application of Soleve to sunburnt skin may be associated with a temporary sensation of tingling or stinging, but this should subside after a few minutes. Treatment should be stopped if tingling/stinging persists.

Occasionally, mild skin rashes, itching or irritation can occur where it is applied. If this is unacceptable, or persists, stop using the product and tell your pharmacist.

Very rarely, the following side effects can happen with ibuprofen, although these are extremely uncommon with products such as Soleve that are applied to the skin.

If you experience any of the following, stop using Soleve immediately, and get medical advice:

- **Allergic reactions** (particularly in people who have a history of asthma or allergic problems), such as:
  - unexplained runny nose and watery eyes, or, in more serious cases asthma or aggravated asthma involving breathing difficulties, wheezing or chest tightness;
  - generalised allergic skin reactions involving itch, swelling, inflammation, redness and perhaps blistering and light sensitivity;
  - other more serious generalised allergic reactions possibly involving unexplained nausea and vomiting, swollen eyes, face or tongue, difficulty swallowing, dizziness or light-headedness. Unconsciousness could perhaps occur in the most serious cases.
- **Kidney problems** (particularly in people who have a history of kidney disease), such as:
  - decreased urine volume;
  - loss of appetite / weight loss;
  - swelling of the abdomen.
- **Problems with the digestive system** (particularly in people who have a history of stomach ulcers etc), such as:
  - stomach pain;
  - heartburn / indigestion.

If any side effects get serious or don't go away, get medical advice.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Tanning and peeling of the skin are normal reactions to sunburn and may occur 4 to 7 days after being burnt.

5. HOW TO STORE SOLEVE

- Keep it out of the sight and reach of children.
- Always replace the cap tightly after use.
- Do not store the product above 25°C.
- Do not use after the expiry date shown on the bottle and the carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Soleve contains

The **active ingredients** are **ibuprofen** (1% w/w) and **isopropyl myristate** (10% w/w).

The **other ingredients** are coconut oil, carbomers, sorbitan laurate, 2-diethylaminoethanol, phenoxyethanol and purified water.

What Soleve looks like and contents of the pack

- The product is a white lotion (emulsion).
- It is available in bottles containing 100 ml.

The Marketing Authorisation holder is Diomed Developments Limited, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

The Manufacturer is DDD Limited, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK.

The Distributor is DDD Limited, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK.

7. RESPONSIBLE BEHAVIOUR IN THE SUN

- **If you do get burnt, avoid further exposure** to the sun until the signs and symptoms have subsided completely. This may take two to three days.
- Too much exposure to the sun in a hot and/or humid environment can cause heat stroke even if the skin is not sunburnt. **If the patient develops a high temperature, is confused or weak, or has convulsions, you must consult a doctor immediately.**
- Children are especially vulnerable to the harmful effects of the sun. **If a baby or small child has been sunburnt, you must get medical advice.**
- Excessive exposure to the sun damages and ages the skin. Prolonged, unprotected exposure to the sun is also linked to skin cancer, which may take more than 20 years to appear.
- Children and people with fair skin who burn easily are especially vulnerable to the harmful effects of the sun.
- It is very important to protect the skin against sun damage.
  - Spend time in the shade between 11am and 3pm.
  - **Sun protection** should be **applied thickly** at least 30 minutes before sun exposure.
  - Sun protection should be at least **SPF 30** and should block both **UVA and UVB rays.**
  - Sun protection should be **re-applied regularly,** especially after swimming.
  - **Sunglasses** should be worn to protect the eyes, and should have **UV filters.**
  - The face and scalp burn readily, so wear a hat with a brim.
  - Cover easily burnt areas such as the shoulders and upper arms.
- There are many situations where you can get burnt without realising it. Clouds, wind and parasols reduce the sensation of heat, but have only a limited effect on the amount of harmful UV rays reaching the skin, and you can still get burnt while on or in the water.
- Your skin may have been sun-damaged before you realised it. The pain and redness of sunburn take several hours (up to a day) to develop fully and are likely to get worse after being first noticed, even if you take corrective measures, such as keeping out of the sun and treating the sunburn.

This leaflet was last revised in November 2014.

To listen to or request a copy of this leaflet in Braille, large print or audio, please call free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information: Soleve, 00173/0167. This is a service provided by the Royal National Institute of Blind People (RNIB).

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ANNEX 3


Keep out of the reach of children
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SOLEVE™ SUNBURN RELIEF CUTANEOUS EMULSION
ibuprofen 1% w/w
isopropyl myristate 10% w/w
for mild to moderate sunburn
• Avoid sunburn: excessive sun exposure damages the skin and may cause skin cancer.
• Protect children from the sun.
• For your safety: SOLEVE is not a sunscreen or sunblock and will not protect your skin from the sun.
SOLEVE™
SUNBURN RELIEF
CUTANEOUS EMULSION
ibuprofen 1% w/w
isopropyl myristate 10% w/w
Soleve is a smooth, white lotion containing ibuprofen, an anti-inflammatory painkiller, and isopropyl myristate, a moisturiser, to relieve the discomfort of mild to moderate sunburn.
DIRECTIONS: Read and retain the enclosed patient information leaflet. Apply a small quantity of lotion to the affected areas. The amount needed depends on the area which is sunburnt, but as a very rough guide, an amount ranging from a 1 penny piece to a 2 penny piece will usually be sufficient. Re-apply as required, up to eight times daily. Allow a minimum of two hours between applications. Do not exceed the stated dose. Wash hands after use, unless treating them. Seek medical advice if symptoms persist.
BEFORE USING SOLEVE:
• Do not use on infected, diseased, damaged or broken skin (this includes skin with sunburn blisters).
• Not to be used if sunburn is severe or covers a large proportion of the body.
• Not to be used on children under the age of 12 years.
• Not to be used during pregnancy or breast-feeding.
• Although there is less risk of Soleve causing the complications that sometimes arise when ibuprofen (or similar anti-inflammatory painkillers) are taken by mouth, patients with asthma, an active peptic ulcer, or a history of kidney problems should seek medical advice before use.
• Do not use in cases of sensitivity to any of the ingredients, or if allergic to aspirin and other painkillers.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Do not store above 25°C. Replace cap tightly after use.
FOR EXTERNAL USE ONLY
100 ml e
PL 00173/0167
Cutaneous emulsion containing ibuprofen 1% w/w and isopropyl myristate 10% w/w as active ingredients.
Also contains: Coconut Oil; Carbomers; Sorbitan Laurate; 2-Diethylaminoethanol; Phenoxyethanol; Purified Water.
Distributed by DDD Ltd, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK on behalf of Soleve Trademark and Product Licence holder, Diomed Developments Ltd, Hitchin, Herts, SG4 7QR, UK.
MADE IN UK
A DIOMED™ PRODUCT
UP13/14/2
for mild to moderate sunburn in adults & children over the age of 12 years
painkilling
moisturising
Soleve is not a sunscreen or sunblock and will not protect your skin from the sun
It is very important to protect the skin against sun damage.
• Spend time in the shade between 11am and 3pm.
• Sun protection should be applied thickly at least 30 minutes before sun exposure.
• Sun protection should be at least SPF 30 and should block both UVA and UVB rays.
• Sun protection should be re-applied regularly, especially after swimming.
• Sunglasses should be worn to protect the eyes, and should have UV filters.
• The face and scalp burn readily, so wear a hat with a brim.
• Cover easily burnt areas such as the shoulders and upper arms.
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SOLEVE™

SUNBURN RELIEF

CUTANEOUS EMULSION

ibuprofen 1% w/w
isopropyl myristate 10% w/w

for mild to moderate sunburn in adults & children over the age of 12 years

- painkilling
- moisturising

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Soleve is not a sunscreen or sunblock and will not protect your skin from the sun

FOR EXTERNAL USE ONLY

UP11/14/2 PL 00173/0167

Avoid sunburn:
excessive sun exposure damages the skin and may cause skin cancer.

Protect children from the sun.

SOLEVE is not a sunscreen or sunblock and will not protect your skin from the sun.

SOLEVE is used to relieve the discomfort of mild to moderate sunburn.

DIRECTIONS:

Read and retain the accompanying patient information leaflet. Apply a small quantity of lotion to the affected areas. The amount needed depends on the area which is sunburnt, but as a very rough guide, an amount ranging from a 1 penny piece to a 2 penny piece will usually be sufficient. Re-apply as required, up to eight times daily. Allow a minimum of two hours between applications. Do not exceed the stated dose. Wash hands after use, unless treating them.
Seek medical advice if symptoms persist.

BEFORE USING SOLEVE:

- Do not use during pregnancy or breast-feeding.
- Do not use on infected, diseased, broken or damaged skin (this includes skin with sunburn blisters).
- Not to be used if sunburn is severe or covers a large proportion of the body.
- Not to be used on children under the age of 12 years.
- Patients with asthma, an active peptic ulcer, or a history of kidney problems should seek medical advice before use.
- Do not use in cases of sensitivity to any of the ingredients, or if allergic to aspirin and other painkillers.
- Keep out of the sight and reach of children.
- Do not store above 25˚C.

Cutaneous emulsion containing ibuprofen 1% w/w and isopropyl myristate 10% w/w. Also contains: Coconut Oil; Carbomers; Sorbitan Laurate; 2-Diethylaminoethanol; Phenoxyethanol; Purified Water.

UP12/14/2

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