

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
2. Before you use Soleve
3. How to use Soleve
4. Possible side effects
5. How to store Soleve
6. Further information
7. General advice on responsible behaviour in the sun

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

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 reach and sight 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 and 200 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.
 - **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 2012.

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).