SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Soleve Sunburn Relief

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 10 mg/g

Isopropyl myristate 100 mg/g

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous Emulsion

White aqueous Lotion

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of pain associated with mild to moderate sunburn in adults and children over the age of 12 years. Mildly 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.

4.2 Posology and method of administration

For adults, the elderly and children over the age of 12 years:

Commencing as soon as possible after the first sign of any sunburn, apply the lotion to the affected area(s) and massage gently into the skin. Repeat as required, if necessary up to 8 times daily, but leaving at least 2 hours between applications. Treatment should be continued for a maximum of two to three days, by which time the symptoms should have subsided. Wash hands after use, unless treating them. In cases where children are to be treated, the lotion should always be applied by an adult.

The lotion spreads easily, and a small amount goes a long way. The amount required depends on the area of sunburn, but generally a circle 2 to 2.5cm in diameter (2 to 4ml) will be sufficient. Individual doses should not exceed 12ml (one capful of the 200ml pack or one and a half capfuls of the 100ml pack), and the maximum daily dose should not exceed 100ml.

Soleve is not recommended for children under the age of 12 years.

4.3 Contraindications

Not to be used if allergic to any of the ingredients, or in cases of hypersensitivity to aspirin, ibuprofen or related painkillers (including when taken by mouth), especially where associated with a history of asthma, rhinitis or urticaria.

Not to be used on areas of skin which are cut or grazed, or in cases of any unrelated skin condition where the skin is broken.

Not to be used concurrently with any other product containing ibuprofen or any other NSAID.

4.4 Special warnings and precautions for use

Soleve is not a sunscreen or sunblock, and will not protect skin from the sun. Care should be taken to prevent further exposure to the sun's harmful rays until the signs and symptoms of the sunburn have completely resolved. Patients should be advised to stay in the shade and keep the affected area(s) completely covered up. This is especially important when the effect of the sun is most intense (between 11 am and 3 pm).

The pain and redness of sunburn have a delayed onset and are likely to worsen after being first noticed. Patients should be reminded that this may happen even after taking corrective measures, such as keeping out of the sun and treating the sunburn, because the signs and symptoms take several hours (up to a day) to develop fully. Cases of severe or extensive sunburn (involving more than 10% of a child's body surface area, or more than 20% of an adult's body surface area) and cases involving obviously blistered skin, may require more comprehensive medical intervention, and such patients should therefore be encouraged to seek medical advice.

Excessive exposure to sunlight in a hot and/or humid environment can also cause heat stroke. If the patient develops a high temperature, is confused or weak, or has convulsions, they should consult a doctor immediately.

Medical advice should be obtained if a baby or small child has been sunburnt.

Keep away from the eyes and mucous membranes.

Although systemic absorption of topically applied ibuprofen is less than for oral dosage forms, patients with asthma, an active peptic ulcer or a history of kidney problems, should seek medical advice before using the lotion.

Patients should be advised against excessive exposure to sunlight of area treated in order to avoid possibility of photosensitivity.

Patients should be encouraged to seek medical advice if symptoms persist or worsen.

Keep out of the reach and sight of children.

For external use only.

The label should include the following warnings: “Do not exceed the stated dose. Not recommended for children under 12 years. For external use only. Not to be used during pregnancy or breastfeeding. Do not use if you are allergic to any of the ingredients or have experienced problems with aspirin, ibuprofen or related painkillers (including when taken by mouth). If symptoms persist consult your doctor or pharmacist. Keep out of the reach and sight of children. Patients with asthma, an active peptic ulcer or history of kidney problems

should consult their doctor before use, as should patients already taking aspirin or other painkillers.

The patient information leaflet will include a section on responsible behaviour in the sun in line with current UK guidance.

4.5 Interaction with other medicinal products and other forms of interaction

Non-steroidal anti-inflammatory drugs may interact with blood pressure lowering drugs, and may possibly enhance the effects of anticoagulants, although the chance of either of these occurring with a topically administered preparation is extremely remote. Where aspirin or other NSAID tablets are taken concurrently, it is important to bear in mind that these may increase the incidence of undesirable effects.

The formulation is designed to resist being washed off whilst swimming or bathing.

4.6 Fertility, pregnancy and lactation

Not to be used during pregnancy or lactation. Although no teratogenic effects have been demonstrated, ibuprofen should be avoided during pregnancy. The onset of labour may be delayed, and the duration of labour increased. Ibuprofen appears in breast milk in very low concentrations, but is unlikely to affect breast-fed infants adversely.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

The initial application of Soleve or other liquid preparations to sunburned skin may occasionally be associated with a temporary sensation of tingling or stinging, but this should subside after a few minutes.

Very rarely, susceptible patients may experience the following side effects with ibuprofen, but these are extremely uncommon when ibuprofen is administered topically. If they occur, treatment should be discontinued:-

Hypersensitivity: hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm, or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

Renal: renal impairment can occur in patients with a history of kidney problems.

Gastrointestinal: side effects such as abdominal pain and dyspepsia have been reported.

Peeling and tanning of the skin are normal reactions to sunburn, and may occur 4 – 7 days after being burnt.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Overdose with a topical presentation of ibuprofen is extremely unlikely.

Symptoms of severe ibuprofen overdosage (e.g. following accidental oral ingestion) include headache, vomiting, drowsiness and hypotension. Correction of severe electrolyte abnormalities should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: M02AA13

Soleve is for topical application. Ibuprofen is a phenylpropionic acid derivative which exerts its anti-inflammatory and analgesic effects directly in tender skin at the site of application, mainly by inhibiting prostaglandin biosynthesis. Soleve also contains isopropyl myristate which is an emollient.

5.2 Pharmacokinetic properties

There do not appear to be any appreciable differences between the oral and topical routes of administration regarding metabolism or excretion of ibuprofen.

There is evidence that percutaneous absorption of topically applied drug substances is not influenced by non-severe sunburn. Accordingly, and bearing in mind the low absolute doses of ibuprofen involved, pharmacokinetic studies on the percutaneous absorption of ibuprofen from Soleve have not been performed.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Coconut Oil

Carbomers

Sorbitan Laurate

2-Diethylaminoethanol

Phenoxyethanol

Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 25ºC

6.5 Nature and contents of container

Polypropylene bottles fitted with a single-holed LDPE dispensing plug and spigotted polypropylene screw cap, containing 100 ml or 200 ml.

6.6 Special precautions for disposal

No special instructions

7 MARKETING AUTHORISATION HOLDER

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UK

8 MARKETING AUTHORISATION NUMBER

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/02/2003 / 10/03/2009

10 DATE OF REVISION OF THE TEXT

18/02/2019