SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Deep Relief
Deep Relief Pain Relief Gel
Deep Relief Anti-Inflammatory Gel

5% w/w / 3% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of gel contains 50 mg (5%) ibuprofen and 30 mg (3%) levomenthol.

Excipient with known effect: propylene glycol.
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Gel for cutaneous administration.

Clear, colourless gel with the odour of menthol.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product is indicated in adults and children aged over 12 years.

Relief of rheumatic pain, muscular aches, pains and swellings such as strains, sprains and sports injuries.

4.2 Posology and method of administration

Posology

For adults, the elderly and children over 12 years

Method of administration

Apply the gel over the affected area and massage gently until absorbed. Repeat as necessary, up to a maximum of three times a day. Not to be repeated more frequently than every four hours.

For each application use about 10 to 40mm (½ to 1½ inches) if using the 20, 30 or 50g sizes and use 40 to 100mm (1½ to 4 inches) (containing 50-125mg Ibuprofen) if using the 15g size.

If no improvement is seen after two weeks, consult your doctor.

For external use only.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1
Those patients known to be hypersensitive to ibuprofen, levomenthol, or any of the ingredients or sensitive to aspirin, or other NSAIDS including when taken by mouth, or asthmatic patients in whom aspirin or non-steroidal anti-inflammatories are known to precipitate asthmatic attacks, rhinitis or urticaria. Use on broken skin or denuded skin. Simultaneous use on the same site with any other topical medicine. Use in the presence of local infection. Use in the last trimester of pregnancy.

4.4 Special warnings and precautions for use

Paediatric population
Not recommended for children under 12 years of age.

The gel should not be used on or near mucous membranes, nor near the eyes.

Avoid contact with inflamed or broken skin. Discontinue use if rash or irritation develops. Not for use with occlusive dressings.

Always try on a small area first.

As it is known that oral Ibuprofen may worsen an existing renal impairment, or aggravate an active peptic ulcer, patients with a history of renal problems or with an active peptic ulcer should seek medical advice before using topical Ibuprofen products.

The hands should be washed after applying the product, unless they are being treated.

Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration.

If anyone swallows the gel he or she should contact his or her doctor or nearest casualty department.

If anyone experiences any unwanted effects, if there is no improvement, or the condition is aggravated, he or she should consult his or her doctor.

By extrapolation from other routes of administration:
Although this is less likely with NSAIDs intended for topical use compared to oral drugs, the use of this product, as with any drug known to inhibit cyclo-oxygenase/prostaglandin synthesis, may impair fertility. In women who have difficulty conceiving or who are undergoing investigation of infertility, withdrawal of this product should be considered.

Keep all medicines out of the sight and reach of children.

For external use only.

Do not store above 25°C

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Concurrent use of aspirin or other NSAIDS may result in an increased incidence of adverse reactions. Due to the low systemic absorption in normal conditions, interactions described for NSAIDS administered orally are unexpected.

Paediatric population
No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

The safety of ibuprofen in pregnancy has not been sufficiently documented in humans. Animal studies with oral treatment did not show teratogenic effects. In case of sufficient systemic concentrations an inhibition of spontaneous labour, premature closure of the ductus arteriousus botalli, increased bleeding complications in the mother and neonate and increased risk of oedema in the mother can be expected.

Topical ibuprofen is not recommended during the first six months of pregnancy and is contraindicated in the last trimester of pregnancy.

Ibuprofen and metabolites are excreted into breast milk so this product is not recommended during nursing.

4.7 Effects on ability to drive and use machines

This product has no influence on the ability to drive and use machines.

No effects are known with topical Ibuprofen.

4.8 Undesirable effects

Skin disorders are most frequently reported: Application site reactions such as, rashes, pruritus and urticaria, drying, reddening, burning sensation, contact dermatitis.

Other systemic undesirable effects of NSAIDs depend on the quantity of gel applied, the treated area, the integrity of the skin, the duration of treatment, the use of occlusive dressings**:** although extremely uncommon when administered topically side effects such as abdominal pain, dyspepsia and renal impairment are possible.

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 of asthma, aggravated asthma, dyspnoea and bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease (see section 4.3).
(c) Assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

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 national reporting system:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Overdosage is unlikely to occur with topical application.

Symptoms of Ibuprofen overdose include headache, vomiting, drowsiness and hypotension.

Severe electrolyte abnormalities should be corrected.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other topical products for joint and muscular pain. ATC Code M02AX

Ibuprofen, a phenylpropionic acid derivative, is a prostaglandin synthetase inhibitor, with analgesic and anti-inflammatory activities when applied topically.

Levomenthol, when applied to the skin, constricts the blood vessels causing a sensation of coldness followed by an analgesic effect. The action of menthol is exerted at the nerve endings of the skin producing mild counter-irritation which is comforting in painful lesions of the muscles, tendons and joints.

Because it is formulated in an aqueous/alcoholic gel, the preparation itself also exerts a soothing and rapid cooling effect when applied to the skin.

5.2. Pharmacokinetic properties

Ibuprofen is applied topically for percutaneous absorption. When applied topically, absorption through the skin has been shown to be about 5% of that taken orally. Systemic concentration reaches a maximum of about 0.6 micrograms per ml some two hours after application.

Levomenthol absorbed through the skin is transported to the liver. Some Phase I metabolism may occur in the skin but most occurs in the liver. The menthol is hydroxylated and then conjugated with glucuronide prior to circulation to the kidneys for excretion in the urine.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, ibuprofen and menthol were devoid of mutgenic activity in vitro and in vivo.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol

Diisopropanolamine

Carbomer

Denatured Ethanol

Purified water

6.2 Incompatibilities

Not applicable to a topical formulation.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5. Nature and contents of container

Collapsible aluminium tube with epoxy resin lining and high density polyethylene cap filled to an average weight of 15, 20, 30 or 50g. The tube is enclosed by a cardboard carton containing a package insert.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

The Mentholatum Company Limited
1 Redwood Avenue
Peel Park Campus
East Kilbride G74 5PE, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00189/0027

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/02/2009

10 DATE OF REVISION OF THE TEXT

01/08/2016