PROFESSIONAL INFORMATION

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1. NAME OF THE MEDICINE

DEEP RELIEF GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g gel contains: Ibuprofen 50 mg

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

DEEP RELIEF is a clear colourless to slightly yellow gel with a menthol odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

DEEP RELIEF is recommended as a topical anti-inflammatory and analgesic intended for the symptomatic relief of acute painful musculo-skeletal conditions caused by trauma such as sports injuries, sprains, strains and contusions.

4.2 Posology and method of administration

Adults, the elderly and children over 14 years of age:

Apply a thin layer of 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 1 to 4 cm of gel (about 50 - 125 mg ibuprofen).

Replace cap tightly. Wash hands after use.

Do not cover the skin with bandages, plaster or any other dressings.

Do not exceed the stated dose.

Use the lowest effective dose for the shortest possible duration of treatment.

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

FOR EXTERNAL USE ONLY.

4.3 Contraindications

DEEP RELIEF is contra-indicated in those patients known to be hypersensitive to ibuprofen or any of the ingredients of DEEP RELIEF, or to aspirin or other NSAIDs (including when taken orally), and in asthmatic patients in whom aspirin or non-steroidal anti-inflammatories (NSAIDs) 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.

Heart failure.

History of gastrointestinal bleeding or perforation (PUBs) related to previous NSAIDs.

Active or history of recurrent ulcer, haemorrhage or perforation.

Not recommended for children under 14 years.

4.4 Special warnings and precautions for use

DEEP RELIEF should not be used on or near mucous membranes or 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.

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Steven-Johnson syndrome, and toxic epidermal necrolysis have been reported.
DEEP RELIEF should be discontinued at the first appearance of skin rash, mucosal lesions, or any sign of hypersensitivity.

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 therefore seek medical advice before using DEEP RELIEF.

The elderly have an increased frequency of adverse reactions to NSAIDs including DEEP RELIEF, especially gastrointestinal perforation, ulceration and bleeding (PUBs) which may be fatal.

When gastrointestinal bleeding or ulceration occurs in patients receiving DEEP RELIEF, treatment with DEEP RELIEF should be stopped.
DEEP RELIEF should be given with caution to patients with a history of gastro-intestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated.

Caution is required in patients with a history of hypertension and/or heart failure as

fluid retention and oedema have been reported in association with oral ibuprofen therapy. In view of ibuprofen's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

The hands must 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 DEEP RELIEF gel is applied to relatively large areas of skin and over a prolonged period, the possibility of systemic side-effects cannot be excluded.

If DEEP RELIEF is swallowed, contact the nearest doctor or hospital.

If any unwanted effects are experienced, or there is no improvement within 14 days, or the condition is aggravated, the patient should consult their healthcare professional.

4.5 Interaction with other medicines and other forms of interaction

Concurrent use of aspirin or other NSAIDs may result in an increased in side-effects.
Simultaneous use of oral ibuprofen with corticosteroids can result in an increased risk of gastrointestinal perforation, ulceration or bleeding (PUBs).
As with oral Ibuprofen, DEEP RELIEF may enhance the effects of anti-coagulants such as warfarin.
Using oral ibuprofen with anti-platelet medicine and selective serotonin reuptake inhibitors (SSRIs) may increase the risk of gastrointestinal bleeding.

Due to the low systemic absorption of ibuprofen in DEEP RELIEF under normal conditions, interactions described above for ibuprofen administered orally are unexpected.

4.6 Fertility, pregnancy and lactation

The safety of this preparation in pregnancy and lactation has not been established.

In the case of sufficient systemic concentrations, inhibition of spontaneous labour, premature closure of the ductus arteriosus botalli, increased bleeding complications in the mother and neonate and increased risk of oedema in the mother can be expected. Regular use of non-steroidal anti-inflammatory medicines during the third trimester of pregnancy, may result in premature closure of the foetal ductus arteriosus in utero, and possibly, in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed and its duration increased.

DEEP RELIEF is not recommended during the first six months of pregnancy and is contra-indicated in the last trimester of pregnancy.

Although it is less likely with DEEP RELIEF that is intended for topical use compared to oral NSAIDs, the use of DEEP RELIEF may inhibit cyclo-oxygenase/prostanglandin synthesis and may impair fertility.
In women who have difficulty conceiving or who are undergoing investigation of infertility, withdrawal of DEEP RELIEF should be considered.

Ibuprofen and metabolites are excreted into breast milk; so, DEEP RELIEF is not recommended during breastfeeding.

4.7 Effects on ability to drive and use machines

No effects on the ability to drive or using machines are known with DEEP RELIEF.

4.8 Undesirable effects

Cardiac disorders:

Less frequent: Oedema, hypertension and cardiac failure.

Respiratory, thoracic and mediastinal disorders:

Frequency unknown: Asthma, aggravated asthma, dyspnoea and bronchospasm.

Gastrointestinal disorders:

Less frequent: Abdominal pain and dyspepsia.

The following gastrointestinal side-effects is applicable to oral ibuprofen:

Frequent: Peptic ulcers, perforation or gastro-intestinal bleeding, nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohns's disease and gastritis.

Hepato-biliary disorders:

Less frequent: Renal impairment.

Skin and subcutaneous tissue disorders:

Frequent: Rashes, pruritis and urticaria, drying, reddening, burning sensation and contact dermatitis, purpura and

angioedema.

Less frequent: Mild erythema and tingling, bullous reactions (including toxic epidermal necrolysis, Steven-Johnson syndrome and erythema multiforme).

General disorders and administrative site conditions:

Frequency unknown: Non-specific allergic reactions and anaphylaxis.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Topical overdosage is unlikely to occur.

Symptoms of DEEP RELIEF overdose include headache, vomiting, drowsiness and hypotension. In the event of accidental overdosage (e.g. in children) treatment is symptomatic and supportive. Severe electrolyte abnormalities should be corrected.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 3.1 Antirheumatics (anti-inflammatory agents).

ATC code: M02AX

Ibuprofen is a phenyl propionic acid derivate. It is a prostaglandin synthetase inhibitor, with analgesic and anti-inflammatory activities when applied topically.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No additional preclinical information, relevant to the indication, is presented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol,

diisopropanolamine,

carbomer,

denatured ethanol (96 %),

levomenthol and

purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at or below 30 °C.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

DEEP RELIEF is presented in collapsible aluminium tubes with epoxy resin lining and high density polyethylene cap filled to an average weight of 100 g. The tube is enclosed by a cardboard carton containing a patient information leaflet.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Mentholatum South Africa (Pty) Ltd

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7945

8 REGISTRATION NUMBER

29/3.1/0654

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10 May 2021

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