PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

DEEP RELIEF, 50 mg/g gel

The active substance per 1 g gel is 50 mg ibuprofen.

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

DEEP RELIEF is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use DEEP RELIEF carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DEEP RELIEF with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What DEEP RELIEF is and what it is used for
2. What you need to know before you use DEEP RELIEF
3. How to use DEEP RELIEF
4. Possible side effects
5. How to store DEEP RELIEF
6. Contents of the pack and other information

1 What DEEP RELIEF is and what it is used for

DEEP RELIEF is an antirheumatic that provides pain relief and reduces inflammation and swelling when rubbed into the skin.

It is used for the symptomatic relief of muscular aches and pain caused by sports injuries, sprains, strains and bruises.

2 What you need to know before you use DEEP RELIEF

Do not use DEEP RELIEF:

- if you are hypersensitive (allergic) to ibuprofen or aspirin or other NSAIDs (nonsteroidal anti-inflammatory medicines that provide pain-killing, fever-reducing and anti-inflammatory effects), or to any of the other ingredients of DEEP RELIEF (listed in section 6)
- if you have asthma and know that aspirin or non-steroidal anti-inflammatory medicines may bring on an asthma attack, rhinitis (inflammation of lining of the nose) or urticaria (itchy skin eruptions or hives)
- on broken skin or chafed or raw skin
- simultaneously on the same site with any other topical medicine
- in the presence of local infection
- in the last trimester of pregnancy
- if you have heart failure
- if you have a history of gastrointestinal bleeding or perforation with previous use of NSAIDs

- if you have an active or history of recurrent ulcer, stomach bleeding or perforation
- if you are younger than 14 years.

Warnings and precautions

Take special care with DEEP RELIEF:

Consult a doctor or healthcare professional before use in the following cases:

- kidney problems
- stomach ulcer
- history of gastrointestinal disease
- history of hypertension or heart failure
- if you are elderly as the possibility of side-effects may be higher, especially gastrointestinal bleeding and perforation.

Discontinue use of DEEP RELIEF

- if skin reactions get bothersome or worse
- if gastrointestinal bleeding or ulcers occur.

Serious skin reactions, some of them fatal, have been reported with the use of NSAIDs like DEEP RELIEF.

Do not use DEEP RELIEF on or near mucous membranes or near the eyes.

Avoid contact with inflamed or broken skin.

Do not cover with a dressing.

Wash your hands after applying DEEP RELIEF, unless your hands are being treated.

To prevent undesirable effects, you must use the smallest effective dose for the shortest possible time.

If DEEP RELIEF is applied over a large area of the skin over a long period of time, it can be absorbed into the body and increase the possibility of undesirable effects.

Contact your healthcare professional if you feel that there is no improvement after 14 days or if the condition becomes worse or if you experience any unwanted effects.

Other medicines and DEEP RELIEF

Always tell your healthcare provider if you are taking any other medicines. (This includes complementary or traditional medicines.)

Using DEEP RELIEF with aspirin or other NSAIDs may increase the possibility of side-effects.

DEEP RELIEF may enhance the effects of anticoagulants (medicines that prevent the clotting of blood) such as warfarin.

Simultaneous use of oral ibuprofen with corticosteroids can increase the risk of stomach ulcers or bleeding.

Also, the simultaneous use of oral ibuprofen with anti-platelet agents and selective serotonin reuptake inhibitors (medicines used as antidepressants) may increase the risk of gastrointestinal bleeding.

However, DEEP RELIEF has low systemic absorption under normal conditions; therefore, the interactions described above for ibuprofen taken orally are not expected for DEEP RELIEF.

Pregnancy and breastfeeding

Do not use DEEP RELIEF if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.
Stop using DEEP RELIEF if you are planning on becoming pregnant or if you have difficulty in conceiving, as it may impair fertility.

Driving and using machines

DEEP RELIEF should not have any effect on your ability to drive or to use machines.

3 How to use DEEP RELIEF

Do not share medicines prescribed for you with any other person.

Always use DEEP RELIEF exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

- Always try DEEP RELIEF on a small area of the skin first.
- This medicine is for adults, the elderly and children older than 14 years.
- Apply 1 to 4 cm gel in a thin layer on the affected area.

- Gently massage until the gel is absorbed.
- Repeat these steps up to three times a day.
- Do not apply more frequently than every four hours.
- Replace cap tightly.
- Wash hands after use.
- Do not cover the skin with bandages, plasters or any other dressing.
- Do not use for longer than two weeks. If no improvement is seen after two weeks, consult your healthcare professional.
- Do not use more than the stated dose. Use the lowest effective dose for the shortest duration of time.
- FOR EXTERNAL USE ONLY.

If you use more DEEP RELIEF than you should

Overdose with DEEP RELIEF is unlikely to occur.

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdose include headache, vomiting, drowsiness and abnormal low blood pressure.

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

In the event of accidental overdose (e.g. in children) treatment is symptomatic and supportive.

4 Possible side effects

DEEP RELIEF can have side effects:

- Itching, reddening of the skin or a rash may occur where you have applied the gel. This is not a cause for concern.
- However, if this gets worse or you experience any other side-effects, discontinue use.

If any of the following happens, stop using DEEP RELIEF and tell your doctor immediately or go to the casualty department at your nearest hospital:

- rash or itching, where you have not applied the gel. This may be due to an allergic reaction to one of the ingredients
- difficulty swallowing or breathing
- asthma attack

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to DEEP RELIEF. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain
- difficulty breathing
- less urine than is normal for you.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- nausea (feeling sick)
- abdominal cramps or stomach pains
- flatulence or wind
- diarrhoea
- constipation
- melaena (abnormally dark stool, containing blood, usually from gastrointestinal bleeding)
- vomiting blood.

These side effects are normally observed with oral ibuprofen, and due to the low risk of absorption of DEEP RELIEF should not be observed with DEEP RELIEF.

Not all side effects reported for DEEP RELIEF are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using DEEP RELIEF, please consult your health care provider for advice.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DEEP RELIEF. You may also report side effects directly to https://www.mentholatum.co.za.

5 How to store DEEP RELIEF

Store at or below 30 °C.

Keep the tube in the outer carton.

Keep the tube tightly closed.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Store all medicines out of reach of children.

6 Content of the pack and other information

What DEEP RELIEF contains

The active substance is 50 mg ibuprofen per 1 g gel.

The other ingredients are carbomer, denatured ethanol 96 %, diisopropanolamine, levomenthol, propylene glycol and purified water.

What DEEP RELIEF looks like and contents of the pack

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

DEEP RELIEF is presented in aluminium tubes of 100 g.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The PI can be found online under Mentholatum SA's website:

https://www.mentholatum.co.za/product-information/.

Namibia:
S1 Reg. no: 13/3.1/0269
Zambia:
PM. Reg. no: To be allocated
Zimbabwe:
P.I.M. Reg. no: To be allocated