PROFESSIONAL INFORMATION

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1. NAME OF THE MEDICINE

MENTHOLATUM DEEP HEAT RUB

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g contains:

Methyl salicylate	12,8 g
Menthol	5,91 g

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

MENTHOLATUM DEEP HEAT RUB is a white to off-white cream with the odour of menthol, methyl salicylate, eucalyptus oil and turpentine oil.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

MENTHOLATUM DEEP HEAT RUB is indicated for the temporary relief if minor aches and pains of muscles and joints associated with arthritis, simple backache, strains and sprains.

4.2 Posology and method of administration

Adults and Children over 5 years

For arthritis: Apply to affected area. Massage gently until absorbed into the skin.

Repeat three to four times a day.

For Sore Muscles: Massage in before exercise to warm up and after exercise to relief muscle soreness or stiffness.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Patients with diabetes or impaired circulation should only use this product on advice of a doctor.

Do not apply to wounds or to damaged or very sensitive skin.

4.4 Special warnings and precautions for use

Avoid contact with the eyes or mucous membranes.

Not to be used on children under 5 years of age.

Use only as directed. If symptoms persist consult a doctor.

Discontinue use if excessive irritation occurs.

Do not wrap, bandage or apply external heat or hot water.

Wash hands thoroughly after use.

FOR EXTERNAL USE ONLY.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been

performed. It is unlikely that treatment with Mentholatum Deep Heat Rub will have any effect on the ability to drive and use machines.

4.8 Undesirable effects

Hypersensitivity reactions may occur.

Side effects similar to that of aspirin can occur.

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

See "Undesirable effects". Treatment is symptomatic and supportive.

In case of accidental ingestion, seek professional assistance or contact a Poison Information Centre immediately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 13.5 Rubefacients.

Mentholatum Deep Heat Rub when applied produces an immediate sensation of warmth due to the rubefacient and counter-irritant properties.

5.2 Pharmacokinetic properties

Mentholatum Deep Heat Rub is for topical administration. No absorption studies have been carried out.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol

Sodium cetyl stearyl sulphate

Eucalyptus oil

Turpentine oil

Propylene glycol

Liquid paraffin

Lanolin anhydrous

Water.

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at or below 25°C.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Aluminium tube filled to an average weight of 15 g, 35 g, 75 g or 100 g with a high-density polyethylene cap enclosed by a cardboard carton. Not all pack sizes may be available.

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

G2268 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

9 December 1975

10 DATE OF REVISION OF THE TEXT

2 November 2020