PROFESSIONAL INFORMATION

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1. NAME OF THE MEDICINE

MENTHOLATUM DEEP HEAT SPRAY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g contains:

Methyl nicotinate	1,59 g
2-Hydroxyethyl salicylate	4,95 g
Ethyl salicylate	4,95 g
Methyl salicylate	0,99 g

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised aerosol multi-dose dispenser for administration to human beings as a topical spray. The spray is a clear liquid with a characteristic smell of methyl salicylate.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Indicated for pain relief and provides temporary relief from the minor pain and stiffness of rheumatism and muscle soreness.

4.2 Posology and method of administration

SHAKE THE CAN BEFORE USE.

Adults and Children over 5 years of age

Spray onto the parts affected when necessary, up to 3 times per day, before or after exercise. Pointing the spray aperture towards the area of pain, holding can about 15 cm from the skin, press the button and spray in 2-3 short bursts. Massage is not required.

Not for use in children under 5 years of age (see CONTRAINDICATIONS).

4.3 Contraindications

Hypersensitivity to methyl nicotinate, 2-hydroxyethyl salicylate, ethyl salicylate and methyl salicylate or to any of the inactive ingredients of Mentholatum Deep Heat Spray.

Hypersensitivity to aspirin or other non-steroidal anti-inflammatory medication (including when taken by mouth) especially where associated with a history of asthma. (See WARNINGS AND SPECIAL PRECAUTIONS)

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

4.4 Special warnings and precautions for use

Use only as directed. FOR EXTERNAL USE ONLY.

Do not apply to broken skin or raw areas.

Consult your doctor before you use Mentholatum Deep Heat Spray if you are pregnant, breastfeeding, asthmatic or use other medication. (See CONTRAINDICATIONS AND PREGNANCY AND LACTATION).

Protect the face when spraying around the neck and shoulders.

Avoid contact with the eyes and inhalation.

Always try on a small area first.

Always use sparingly as over-use may cause discomfort, particularly in persons with sensitive skins, or if used in hot weather or after a bath. Exercise care with sensitive

skins.

If symptoms persist consult your doctor. Discontinue use if irritation or other unwanted effect occur.

4.5 Interaction with other medicinal products and other forms of interaction

No adequate controlled interaction studies have been undertaken. Excessive use of Mentholatum Deep Heat Spray may increase the effect of anticoagulants like warfarin and antiplatelet medicines. It is therefore advisable that caution be exercised with patients who are on anticoagulants such as warfarin or antiplatelet medicines including aspirin.

4.6 Fertility, pregnancy and lactation

The safety of Mentholatum Deep Heat Spray in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Skin and subcutaneous tissue disorders:

Less frequent: Urticaria, skin burns, blisters, skin reactions such as redness, irritation, burning sensation and rashes, eczema and skin discolouration.

Immune system disorders:

Less frequent: Hypersensitivity and allergic reactions.

General disorders and administrative site conditions:

Less frequent: Application site inflammation, pain, burns, redness and skin sensitivity.

Nervous system disorders:

Less frequent: Burning sensation, flushing and headache.

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 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

Ingestion of relatively small amounts of methyl salicylate as in Mentholatum Deep Heat Spray may cause severe poisoning and death. The methyl salicylate may give rise to irritation of the gastric mucosa and dyspepsia, erosion, ulceration, haematemesis and melaena. Systemic poisoning may occur from application to large areas of the skin. Mild symptoms of intoxication could include dizziness, tinnitus, sweating, nausea and vomiting and mental confusion. More serious signs of toxicity include hyperventilation, fever ketosis and respiratory alkalosis and metabolic acidosis. Coma, cardiovascular collapse and respiratory failure may result.

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 13.5 Dermatological preparations – Rubefacients.

Mentholatum Deep Heat Spray has counter-irritant properties.

5.2 Pharmacokinetic properties

Not applicable. The product is for topical administration. No absorption studies have been carried out with this product.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol

Butane B46

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C and protect from direct sunlight.

Do not pierce or burn, even when empty.

Do not spray on a naked flame or any incandescent material.

6.5 Nature and contents of container

Pressurised aerosol multi-dose dispenser with contents of 150 ml or 250 ml. The spray is a clear liquid with a characteristic smell of methyl salicylate.

6.6 Special precautions for disposal

None

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

Q/13.6/264

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

17 October 1983

10 DATE OF REVISION OF THE TEXT

March 2021