

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Mentholatum Deep Heat Rub
Tesco Heat Rub
Deep Heat Heat Rub
Boots Heat Rub

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Methyl salicylate	12.80% w/w
Menthol	5.91% w/w
Eucalyptus oil	1.97% w/w
Turpentine oil	1.47% w/w

For excipients see 6.1

3 PHARMACEUTICAL FORM

Cutaneous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of:

Muscular pains and stiffness, including backache, sciatica, lumbago, fibrositis, rheumatic pain, chilblains, bruises and sprains including those caused by minor sports injuries.

4.2 Posology and method of administration

For adults and children over 5 years

For topical administration.

Directions for use: - apply a thin layer to the affected part with gentle massage 2 to 3 times daily.

Can be used before or after exercise.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Hypersensitivity to aspirin, ibuprofen or other non-steroidal anti-inflammatory drugs (including when taken by mouth) especially where associated with a history of asthma.

4.4 Special warnings and precautions for use

Pregnancy and breast-feeding – avoid use unless necessary (see section 4.6).

Asthma – caution is required as salicylates may provoke bronchospasm in patients with asthma (see section 4.3).

Interactions – salicylates can increase the effect of anticoagulants and anti-platelet medications (see section 4.5).

The label/leaflet will include the following:

Do not use if you are allergic to any of the ingredients or painkillers such as aspirin, ibuprofen and other NSAIDs. Consult your doctor before use if you are pregnant, breast-feeding, asthmatic or on any prescribed medicines. For external use and only on unbroken skin. Avoid contact with the eyes and sensitive areas of skin. Always try on a small area first. Some people may experience discomfort particularly those with sensitive skin or if used in hot weather or after a bath. Not for use with occlusive dressings. Wash hands immediately after use. Discontinue use if excessive irritation or other unwanted effects occur. If symptoms persist consult your doctor. Not to be used on children under 5 years of age. Keep all medicines out of the reach and sight of children.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.”

4.5 Interaction with other medicinal products and other forms of interaction

Although no adequately controlled interaction studies have been undertaken, it is possible that excessive use of topical salicylates may increase the effect of coumarin anticoagulants and antiplatelet medications. Patients who are taking coumarin anticoagulants or antiplatelet medications, including aspirin, should therefore exercise caution.

4.6 Pregnancy and lactation

There are no adequate data from the use of this product during pregnancy or breast-feeding upon which to base specific advice. Salicylates are aspirin-like substances; therefore similar cautions as appropriate for aspirin are advised. As with all medicinal products, use during pregnancy or breast-feeding should be avoided unless considered necessary.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

It is possible that skin burns, blisters and temporary skin reactions such as redness, burning sensation and rashes may occur.

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 Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdose is unlikely when used as recommended. If applied to a large area of skin, or in the unlikely event of oral ingestion, the product may cause systemic adverse effects depending on the amount absorbed.

Treatment of overdose should be supportive and symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Methyl salicylate is an aspirin like drug used for pain relief.

Turpentine oil and Eucalyptus oil acts as rubefacients.

Menthol when applied topically provides analgesia.

5.2 Pharmacokinetic properties

The product is for topical administration. No absorption studies have been carried out with this product. Data from the published literature on the active ingredients can be summarised as follows:

Methyl salicylate is readily absorbed from topical preparations and this absorption is enhanced by heat, exercise, occlusion and disruption to the skin surface. Rapid local hydrolysis to salicylic acid in tissues results in low systemic plasma concentrations of methyl salicylate after topical application. Topical application of methyl salicylate is therefore likely to exert local effects only. Systemic salicylic acid becomes extensively protein bound in an inactive form and the free active form is metabolised or excreted unchanged in the urine.

Pharmacokinetic information following topical application of menthol is limited. Menthol is absorbed, across the skin with relatively low systemic plasma concentrations indicating that the effects of topical menthol are likely to be predominantly local in nature. There is thought to be some metabolism of topical menthol in the skin, but the majority is metabolised by the liver which converts the

lipid soluble menthol into four water soluble metabolites that are excreted in the urine.

Very little is known about the pharmacokinetic properties of eucalyptus and turpentine oils following topical application.

5.3 Preclinical safety data

No toxicology testing of the product has been undertaken. However, all the active ingredients are subject to monographs in the British and European Pharmacopoeias and are documented in Martindale, The Complete Drug Reference.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium cetostearyl sulphate

Cetostearyl alcohol

Propylene glycol

Wool fat (Lanolin)

Liquid paraffin

Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Aluminium tube filled to an average weight of 35g, 42g, 67g or 100g with a high density polyethylene cap enclosed by a cardboard carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

The Mentholatum Company Limited

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East Kilbride

G74 5PE

Scotland

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00189/5002R

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

24 January 1995

10 DATE OF REVISION OF THE TEXT

14/01/2025