SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Deep Heat Maximum Strength
Deep Heat Max Strength

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Methyl Salicylate	30.00% w/w
Menthol	8.00% w/w

Excipients of known effect: Sodium Lauryl Sulphate. For a full list of excipients see section 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, bruises and sprains.

4.2 Posology and method of administration

Apply a thin layer with gentle massage to the affected area 2 to 3 times daily.

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

4.3. Contra-Indications

Hypersensitivity to any of the ingredients.

Hypersensitivity to aspirin 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

The label will state:

Do not use if you are allergic to any of the ingredients. Do not use if you have a history of asthma associated with allergic reaction to aspirin or other painkilling medicines known as non-steroidal anti-inflammatory drugs. Check with your doctor if you are unsure.

Consult your doctor before use if:

- you are pregnant or breast feeding
- you are on blood thinning medicines

For external use and only on unbroken skin. Always try on a small area first. Avoid contact with the eyes and sensitive areas of the skin.

Some people may experience local discomfort if used during hot weather or after a hot bath.

Not for use with occlusive dressings.

Wash hands thoroughly after use.

Discontinue use if excessive irritation occurs.

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

Keep all medicines out of the reach and sight of children.

If symptoms persist consult your doctor.

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. It is therefore advisable that caution be exercised with 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. 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. The patient labelling information will incorporate text to advise pregnant or breast-feeding women to consult their doctor before use.

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 effects depending on the amount absorbed.
Treatment of overdose should be supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Menthol and methyl salicylate function as counter-irritants.

5.2. Pharmacokinetic Properties

None stated.

5.3. Pre-clinical Safety Data

The ingredients are subject to monographs in the British and European Pharmacopoeias and are documented in Martindale, the Extra Pharmacopoeia. Therefore no pre-clinical data is included with this application.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan stearate
Polyoxyethylene hexadecyl ether
Glyceryl stearate
Sodium lauryl sulphate
Poloxamer 407
Water

6.2. Incompatibilities

None stated

6.3. Shelf-Life

3 years

6.4 Special precautions for storage

Store below 25^{o}C.

6.5. Nature and Content of Container

Aluminium tube with a high-density polyethylene cap enclosed by a cardboard carton.

Pack sizes: 35g

6.6. Instruction for Use, Handling and Disposal

None

7. MARKETING AUTHORISATION HOLDER

The Mentholatum Company Limited
1 Redwood Avenue
Peel Park Campus
East Kilbride
G74 5PE
Scotland
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00189/0016

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

18 September 1985

10 DATE OF REVISION OF THE TEXT

09/01/2025