Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mentholatum Deep Heat Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients - contains wool fat (lanolin) 0.5% w/w, cetostearyl alcohol 18% w/w and propylene glycol 1.0% w/w.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream
White cream with an odour of menthol and methyl salicylate.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

In the local management of the symptoms of fibrositis, muscle strains and arthroses.

4.2 Posology and method of administration

For adults and children over 5 years.

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

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1
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

Do not use if you are allergic to any of the ingredients or medicines like aspirin. 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. Wash hands immediately after use.

This medicine contains 1mg propylene glycol in each 100mg which is equivalent to 10mg in 1g of cream. Propylene glycol may cause skin irritation.

This medicine contains wool fat (lanolin) and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

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 sight and reach of children.

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 anti-platelet medications. It is therefore advisable that caution be exercised with patients who are on coumarin anticoagulants or antiplatelet medications, including aspirin.

4.6 Fertility, pregnancy and lactation

There are no adequate data for the use of this product during pregnancy of breast-feeding upon which to base specific advice. Safety has not been established during pregnancy and lactation. Patients should seek advice from their doctor before using the product. 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

Irritation of the skin (redness, burning, swelling, blistering) may occur. Burns at application site: not known (frequency cannot be estimated from the available data). There may also be more severe allergy reported (urticaria etc).

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Methyl salicylate is absorbed through the skin and is used for the relief of pain in rheumatic condition.

Turpentine oil when applied topically acts as a rubefacient.

Eucalyptus oil when applied topically acts as a rubefacient and may also be used by inhalation in combination with menthol to relieve nasal congestion.

5.2 Pharmacokinetic properties

The product is for topical administration. No absorption studies have been carried out with this product. Like other salicylates, methyl salicylate may be absorbed through intact skin.

5.3 Preclinical 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 are included with this application.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium cetostearyl sulfate
Cetostearyl alcohol

Propylene glycol
Wool fat (lanolin)
Liquid paraffin
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube, with an epoxy/phenolic lining, of 35g, 67g or 100g with a high density polyethylene screw cap enclosed by a cardboard carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

The Mentholatum Company (Ireland) Limited
Ground Floor
71 Baggot Street Lower
Dublin 2
D02 P593
Ireland

8 MARKETING AUTHORISATION NUMBER

PA25197/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 July 1990

Date of last renewal: 16 July 2010

10 DATE OF REVISION OF THE TEXT

October 2023