

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Mentholatum Deep Heat Spray

Superdrug Heat Spray

Tesco Heat Spray

Deep Heat Heat Spray

Deep Heat Pain Relief Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Methyl Nicotinate 1.60 % w/w

2-Hydroxyethyl Salicylate 5.00 % w/w

Methyl Salicylate 1.00 % w/w

Ethyl Salicylate 5.00 % w/w

For excipients see 6.1.

3 PHARMACEUTICAL FORM

A pressurised container containing a clear colourless cutaneous spray solution with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of muscular pain, bursitis and tendinitis, including rheumatic pain, strains, sprains, fibrositis, lumbago and sciatica.

Spray onto the affected parts when necessary before and after exercise.

4.2 Posology and method of administration

Adults and Children over 5 years of age

Hold spray aperture about 15 centimetres (6 inches) from the skin of the affected area. Spray in 2-3 short bursts up to 3 times a day.

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

4.3 Contraindications

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

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 only. Not to be sprayed onto broken skin. Avoid inhalation and contact with the eyes and sensitive areas of skin. Always try on a small area first. Always use sparingly since some people may experience discomfort particularly in those with sensitive skin or if used in hot weather or after a bath. Protect the face when spraying around the neck and shoulders. 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.

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 Fertility, 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. 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

Not applicable

4.8 Undesirable effects

It is possible that skin burns, blisters, allergic reactions 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.

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 spray 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 Nicotinate	}	Rubefacient by peripheral vasodilator effect
2-Hydroxyethyl Salicylate	}	
Ethyl Salicylate	}	Absorption through the skin to provide local
Methyl Salicylate	}	systemic anti-inflammatory effect

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

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

Propan-2-ol
Butane

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C. Protect from sunlight and do not expose to temperatures exceeding 50°C.

6.5 Nature and contents of container

Tinplate aerosol container, filled to 100g (150ml), 120g (180ml) or 125g (190ml).

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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Peel Park Campus
East Kilbride
G74 5PE
Scotland
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00189/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/02/1999

10 DATE OF REVISION OF THE TEXT

20/02/2017