

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mentholatum Deep Heat Spray, cutaneous spray solution

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 a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution

Clear, colourless 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.

4.2 Posology and method of administration

Adults and Children over 5 years of age:

Spray onto the parts affected when necessary, before or after exercise.

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 per day.

Children 5 years of age and under:

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 the skin. Always try on a small area first. Always use sparingly since some people may experience discomfort particularly 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 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 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 to:

Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6767836
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

4.9 Overdose

Overdosage 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

Pharmacotherapeutic group: Topical Products for Joint and Muscular Pain
ATC code: M02AC.

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

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

No further statements regarding pre-clinical safety are included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl Alcohol

Butane

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 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 150 ml (100g).

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

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 October 1993

Date of last renewal: 18 October 2008

10 DATE OF REVISION OF THE TEXT

September 2023