

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Deep Freeze Cutaneous Spray Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Levomenthol	2.00% w/w
n-Pentane	40.00% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray solution.
A pressurized aerosol, multi-dose dispenser

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of muscular pain

4.2 Posology and method of administration

For adults and children over 6 years

The usual dose is 2 to 3 jets at 30 second intervals to a maximum of 3 treatments daily. The container should be held 6 inches from the affected areas and used for 3 to 5 seconds only.

Avoid excessive use.

Children under 6 years

Not to be used on children under 6 years of age.

4.3 Contraindications

None known.

4.4 Special warnings and special precautions for use

Do not use on broken or inflamed skin. Avoid use on head, digits or sensitive areas. When used near the face, the eyes, nostrils and mouth should be adequately screened. Application should be carried out in a well-ventilated space. Inhalation should be avoided. If symptoms persist, consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

Not applicable

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

None known

4.9 Overdose

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

When pentane impinges on the skin it evaporates and causes a cooling sensation. Menthol, when applied topically, causes a sensation of cold followed by analgesia, which is comforting in the relief of muscular pain. The feeling of comfort when the spray is of benefit to the patient.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

No safety issues became evident during the course of these studies

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethyl ether
Ethanol

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

3 years

6.4 Special precautions for storage

Do not store above 25°C.
Protect from sunlight.

6.5 Nature and contents of container

Tinplate aerosol can internally plain filled to 135g.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

The Mentholatum Company Limited
1 Redwood Avenue
Peel Park Campus
East Kilbride
G74 5PF
Scotland

8 MARKETING AUTHORISATION NUMBER

PA76/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th October 1989

Date of last renewal: 24th October 2004

10 DATE OF REVISION OF THE TEXT

December 2004