Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Deep Freeze Cold Gel 2.0 % w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Racemic Menthol 2.0% w/w

Methyl parahydroxybenzoate (E218) 0.18% w/w
Propyl parahydroxybenzoate (E216) 0.02% w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gel.
Smooth, clear, blue gel with odour of menthol.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of pain in muscles, tendons and joints.

4.2 Posology and method of administration

Adults (including the elderly)
Gently massage Deep Freeze Cold Gel into the affected area 3-4 times daily

Children (over five years)
Apply to the affected area 3-4 times daily

Children (under five years)
Not recommended

Directions for use
For topical application.

Apply over the affected area. Massage gently until completely absorbed into the skin.

4.3 Contraindications

Hypersensitivity to any of the components of the formulation.

4.4 Special warnings and precautions for use

Keep all medicines out of the sight and reach of children.
For external use only.
Hands should be washed immediately after use.
Avoid contact with eyes, mucous membranes and inflamed or broken skin.
Not for use with occlusive dressings.
May cause allergic reactions (possibly delayed).
Repeated application may give rise to hypersensitivity.
Discontinue use if any rash appears.
If symptoms persist consult your doctor.

4.5 Interaction with other medicinal products and other forms of interactions

No interactions are known.

4.6 Fertility, pregnancy and lactation

Studies in pregnant animals at high oral doses revealed no foetal abnormalities. Although there are no formal studies in humans, there is no known reason why this product may not be used during pregnancy or by Breast-feeding mothers.

4.7 Effects on ability to drive and use machines

No effects on driving or the use of machinery are known.

4.8 Undesirable effects

Racemic Menthol may give rise to hypersensitivity reactions including contact dermatitis.

May cause allergic reactions (possibly delayed).

Although not recommended for children under 5 years nor for use on mucous membranes, use of the product on the nostrils of infants may result in apnoea and collapse.

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, Earlsfort Terrace, IRL – Dublin2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: http://www.hpra.ie/; E-mail: medsafety@hpra.ie.

4.9 Overdose

Systemic side effects such as nausea, vomiting and ataxia are not thought to be a problem as significant absorption does not occur after topical application.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Racemic Menthol, when applied to the skin, has a direct effect on dermal cold thermoreceptors, causing a sensation of coolness. This is followed by a counterirritant effect which produces analgesia.

5.2 Pharmacokinetic properties

Racemic Menthol absorbed through the skin is transported to the liver. Some Phase I metabolism may occur in the skin but most occurs in the liver. The menthol is hydroxylated and then conjugated with glucuronide prior to circulation to the kidneys for excretion in the urine.

5.3 Preclinical safety data

There are few published animal toxicology studies employing topical menthol. Those which have been published confirm a wide safety margin between the concentration of menthol in Deep Freeze Cold Gel and concentrations which resulted in adverse effects in these topical animal toxicology studies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl Alcohol
Carbomer
Triethanolamine 85%
Purified Water
Patent Blue V (E131)
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Printed, collapsible aluminium tube with a high molecular weight epoxy resin lining. The tube is closed by a membrane nozzle and a high density polyethylene cap which has a recessed piercer.

The tubes are filled to an average weight of 35g or 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

Colep Laupheim GmbH & Co KG
Fockestrasse 12
Germany

8 MARKETING AUTHORISATION NUMBER

PA22761/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th March 1999

Date of last renewal: 19th March 2009

10 DATE OF REVISION OF THE TEXT

June 2019