

POLAR ICE MENTHOLGEL

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal Product

POLAR ICE MENTHOLGEL

2. Qualitative and quantitative composition

Menthol BP.....2.5% w/w

Colour: Brilliant Blue FCF Supra (C.I. NO: 42090)

Gel Base Q.S.

3. Pharmaceutical form

Gel

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

Posology

Gently massage Menthol Gel into the affected area 3-4 times daily

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.

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4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions.

4.6 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

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.

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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

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

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 menthol Gel and concentrations that resulted in adverse effects in these topical animal toxicology studies.

6. Pharmaceutical particulars

6.1 List of excipients

1. Carbopol - 940 USP NF
2. Menthol BP
3. Camphor BP
4. Propylene glycol BP
5. Sodium Methyl Paraben BP
6. Sodium Propyl Paraben BP
7. Disodium EDTA BP
8. Imidurea USP NF
9. Isopropyl alcohol BP
10. Polysorbate 20 BP
11. Triethanolamine BP
12. Colour Brilliant Blue IHS
13. Purified Water BP

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a. Incompatibilities

Not applicable.

b. Shelf life

3 years

c. Special precautions for storage

Store below 30⁰ C, Protect from sunlight.

d. Nature and contents of container

50g Lami Tube.

e. Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Manufacturer Name

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8. Marketing Authority

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