

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

4head 90 % w/w cutaneous stick

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Levomenthol 90.0 % w/w

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous Stick

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the relief of headaches.

4.2. Posology and Method of Administration

4head is to be applied gently to the forehead. To be used as required, but excessive use avoided. If any symptoms persist or worsen, seek medical advice. For external topical application only.

4.3. Contraindications

Not recommended in patients where there is a known hypersensitivity to menthol.

4.4. Special Warnings and Special Precautions for Use

Keep away from the eyes, levomenthol is irritant if allowed to come into contact with the eyes. For single patient use only. For topical use - not to be taken.

4.5. Interactions with other Medicinal Products and other forms of Interaction

None.

4.6. Pregnancy and Lactation

There is no information on safety when used during pregnancies and breast feeding, but there should be no hazard when applied as advised.

4.7. Effects on Ability to Drive and Use Machines

None.

4.8. Undesirable effects

Menthol may give rise to hypersensitivity reactions including contact dermatitis. Because levomenthol is volatile, in rare cases it may cause temporary, mild watering of the eyes.

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 at: www.mhra.gov.uk/yellowcard.

4.9. Overdose

If accidentally ingested menthol is reported to cause severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness and coma. Treatment for accidental ingestion is by emptying the stomach by gastric lavage. A saline laxative and activated charcoal should be administered. Convulsions may be controlled by the slow intravenous administration of diazepam. Haemodialysis with a lipid dialysate has been employed.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Applied to the skin, menthol dilates local blood vessels, causing a sensation of coldness, followed by an analgesic effect.

5.2. Pharmacokinetic Properties

After absorption, menthol is excreted in the urine and bile as the glucuronide.

5.3. Pre-clinical Safety Data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 20000

Peppermint oil

6.2. Incompatibilities

None known.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

To be kept away from heat. (Melts at about 49 - 56°C).

6.5 Nature and contents of container

Plastic base holding 3.6 g of product in a cone, with screw-on plastic cover.

6.6. Instruction for Use, Handling and Disposal

To be applied as directed. For single patients use only.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

PL 00173/0193.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

12 June 2002

10 DATE OF REVISION OF THE TEXT

10/05/2018