

4head Cutaneous Stick

Summary of Product Characteristics Updated 17-Dec-2020 | Diomed Developments Limited

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 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 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 Interaction with other medicinal products and other forms of interaction

None

4.6 Fertility, 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 Preclinical 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 Special precautions for disposal and other handling

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

7. Marketing authorisation holder

Diomed Developments Limited

T/A Dermal Laboratories

Tatmore Place

Gosmore

Hitchin

Hertfordshire SG4 7QR

UK

8. Marketing authorisation number(s)

PL 00173/0193

9. Date of first authorisation/renewal of the authorisation

12 June 2002/12 January 2009 (unlimited validity)

10. Date of revision of the text

10/05/2018

Company Contact Details

Diomed Developments Limited

Address

Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR

WWW

www.diomedgroup.co.uk

Telephone

+44 (0)1462 458 866