

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Anethaine Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tetracaine Hydrochloride BP 1% w/w.

3 PHARMACEUTICAL FORM

25 g of a smooth white oil in water cream for topical application.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Anethaine Cream gives prompt temporary relief from itching and stinging in insect bites, stings and nettle rash.

4.2 Posology and method of administration

Route of administration:

Anethaine is applied topically to the affected area.

Smooth Anethaine onto affected area. Repeat as needed. Two or three times daily

4.3 Contraindications

Not suitable for infants under three years of age.

Do not apply to broken skin.

Do not get Anethaine into the eyes.

For external use only.

4.4 Special warnings and precautions for use

The packaging will contain the following warnings:

If irritation or inflammation persists, stop using Anethaine and seek medical advice. Keep Anethaine out of the reach of children. Not for prolonged use.

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Bergamot Oil may increase sensitivity to UV light (natural and artificial sunlight).

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, Pregnancy and lactation

No restrictions necessary.

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

Tetracaine is a potent local anaesthetic of the ester type which is used for surface and spinal anaesthesia.

5.2 Pharmacokinetic properties

Tetracaine is absorbed through mucous membranes and damaged skin. It is hydrolysed by plasma esterases to p-aminobenzoic acid and other metabolites, which are excreted mainly by the kidney.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether Ph. Eur.
Cetostearyl Alcohol BP
Diethylene Glycol Monostearate HSE
Liquid Paraffin BP
Glycerol BP
Bergamot Oil 34869 HSE
Purified Water BP

6.2 Incompatibilities

None known.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Internally lacquered aluminium, blind end tubes closed with a polyolefin cap in a cardboard outer. Pack size 25g.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Cambridge Healthcare Supplies Limited
Unit 1 Chestnut Drive
Wymondham
Norfolk
NR18 9SB

8 MARKETING AUTHORISATION NUMBER(S)

PL 16794/0018

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th April 2002

10 DATE OF REVISION OF THE TEXT

17/09/2024