

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hedrin® 4% cutaneous solution

Packaging to state: Hedrin 4% lotion dimeticone

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dimeticone 4% w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous solution

Hedrin is a clear, colourless liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hedrin is indicated for the eradication of headlice infestations

4.2 Posology and method of administration

Adults and children (aged six months and above)

For topical external use only

Apply sufficient lotion to cover dry hair from the base to the tip to ensure that no part of the scalp is left uncovered. Work into the hair spreading the liquid evenly from roots to tips. Allow hair to dry naturally. Hedrin should be left on hair for a minimum of 8 hours or overnight. Wash out with normal shampoo, rinsing thoroughly with water. Repeat the treatment after seven days.

Children under the age of six months should only be treated under medical supervision.

4.3 Contraindications

Hypersensitivity to any of the ingredients

4.4 Special warnings and precautions for use

Discontinue at the first appearance of a skin rash or any other signs of local or general hypersensitivity. Should any signs of hypersensitivity occur (e.g. rashes, urticaria, generalised pruritus, breathing difficulties), the product

should be shampooed off immediately, and if symptoms do not resolve, medical advice sought.

For external use only.

Avoid contact with the eyes but if accidentally introduced into the eyes, flush with water.

Hedrin 4% cutaneous solution is combustible when on the hair and in direct contact with an open flame or other source of ignition; therefore during treatment hair should be kept away from open flames or other sources of ignition.

The labels and leaflets will state:

“Warning:

Keep hair away from sources of ignition, especially naked flames and burning cigarettes, whilst being treated with Hedrin®. Treated hair can readily burn if ignited”.

4.5 Interaction with other medicinal products and other forms of interaction

Dimeticone is not known to interact with other drugs

4.6 Pregnancy and lactation

There is no data to suggest that Hedrin may not be used in pregnancy.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Dimeticone is usually well tolerated.

Minor adverse events include skin irritation, an itchy or flaky scalp and irritation around the eyes.

Single cases of hair loss have been reported.

Signs of hypersensitivity reactions including rash, urticaria, generalised pruritus, and breathing difficulties.

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

There are no known recognised symptoms of overdose.

It is unlikely that Hedrin will enter the bloodstream via scratched skin however if this does occur, available data suggests it will be rapidly eliminated unchanged. If the lotion were to be accidentally ingested, again, the available data suggests that there are no specific safety concerns.

No special procedures are likely to be needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The solution contains dimeticone, which is used in many pharmaceutical and cosmetic preparations. A 4% concentration has been found to affect the physico-physiological activity of lice. It is less effective in its ovicidal activity and therefore two applications 7 days apart are required.

Hedrin contains no neurotoxic organophosphate insecticides and therefore does not work by acting on specific enzymes within the louse. The Hedrin solution acts on the lice by a physical process to cover the lice and disrupt the ability of the lice to manage its water balance so that treated insects fail to excrete surplus water. Hedrin activity is not diminished in insecticide resistant head lice.

5.2 Pharmacokinetic properties

Hedrin is applied topically to the affected area but there is little or no absorption of Hedrin through the skin.

5.3 Preclinical safety data

There are no further relevant data

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cyclomethicone 5

6.2 Incompatibilities

None known

6.3 Shelf life

Three years, when stored unopened

6.4 Special precautions for storage

This product does not require any special storage conditions

6.5 Nature and contents of container

HDPE dropper containers with screw caps; 150ml.

HDPE containers incorporating plastic trigger spray, cap and PE dip tube; 120ml capacity.

Not all packs may be marketed

6.6 Special precautions for disposal

Care should be taken as the product may cause a slip hazard if accidentally spilt onto smooth surfaces

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd

Linthwaite

Huddersfield

HD7 5QH

United Kingdom

8 MARKETING AUTHORISATION NUMBER

PL 00240/0345

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/07/2011

10 DATE OF REVISION OF THE TEXT

04/09/2019