

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lyclear Creme Rinse 1% w/w Cutaneous solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 10mg permethrin

Excipients: Contains Cetyl Alcohol 2.05% w/w, Methyl Parahydroxybenzoate (E218) 0.2% w/w, Propyl Parahydroxybenzoate (E216) 0.08% w/w and Propylene Glycol 0.0784% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.

An orange coloured cream rinse.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of *pediculosis capitis*.

4.2 Posology and method of administration

Topical preparation – applied to scalp and hair.

Adults and Children over 6 months of age

Lyclear Crème Rinse should be used after hair has been washed with a mild non conditioning shampoo and towelled dry. The bottle should be shaken thoroughly and enough Lyclear Crème Rinse applied to saturate the hair and scalp. Particular attention should be given to areas behind the ears and at the nape of the neck.

Lyclear Crème Rinse should be left on the hair for 10 minutes before rinsing the hair thoroughly with water. The hair should then be dried in the usual way.

One bottle of Lyclear Crème Rinse is sufficient for shoulder length hair of average thickness. More may be applied if required and, although no maximum dose has been defined, it is unlikely that two bottles will be required for any one course of treatment. If necessary, a second application can be done 7 or 14 days afterwards.

Residual activity may persist for up to six weeks.

It is not necessary to remove dead eggs or nits except for cosmetic purposes. A fine toothed comb may be used if desired.

Use in the Elderly

Lyclear Crème Rinse is suitable for use in the elderly.

4.3 Contraindications

Use in individuals with a known hypersensitivity to the product, its components, other Pyrethroids and Pyrethrins.

4.4 Special warnings and precautions for use

Lyclear Crème Rinse may be used as normal in asthmatics, however, contact your doctor or pharmacist before commencing treatment if you have any particular concerns.

Neither Permethrin nor Lyclear Crème Rinse are irritants to the eyes. However, should Lyclear Crème Rinse be accidentally introduced into the eyes, rinse immediately with plenty of water.

Children under 6 months of age should be treated on the advice of a doctor.

Nursing staff who routinely use Lyclear Crème Rinse may wish to wear gloves and avoid any possible irritation to the hands.

Permethrin is not affected by the chlorine in swimming baths, so normal swimming activities may continue after use.

As for other products used for the treatment of head lice, resistance can occur. After one week the result of the treatment is checked. If one finds still living lice, one can repeat the treatment with the same product. If after 14 days it is certain that the infestation is still active, it is best to switch to another active product.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions with permethrin.

4.6 Fertility, pregnancy and lactation

Reproduction studies have been performed in mice, rats and rabbits (200-400 mg/kg/day orally) and have revealed no evidence of impaired fertility or harm to the foetus due to permethrin. There are however, only very limited data on the use of permethrin in pregnant women.

Because animal reproduction studies are not always predictive of the human response, treatment should be considered during pregnancy only if clearly needed.

Studies following oral administration of permethrin in cattle have indicated that very low concentrations of permethrin are excreted in milk. However, it is not known whether permethrin is excreted in human milk. Whilst it is unlikely that the concentrations of permethrin in the milk will present any risk to the infant, consideration should be given to withholding treatment during nursing or temporarily discontinuing nursing.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

General Summary of the Most Important Side Effects

Lyclear Crème Rinse is generally well tolerated with a low potential for inducing skin reactions. In a few individuals erythema, rash, pruritus and/or irritation of the scalp has been reported following application of the Crème Rinse, but as an infection with head lice is often associated with such scalp irritation, it is difficult in most instances to determine the underlying cause.

If severe or prolonged signs and symptoms of scalp irritation, skin discomfort, or other undesirable effects occur in association with the use of Lyclear Crème Rinse it should be brought to the attention of a doctor or pharmacist.

Very rarely cases of alopecia have been reported.

Direct contacts should be checked for signs of head lice infection and treated if necessary.

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 HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose**Signs and Symptoms**

There are no reports of overdosage with Lyclear Crème Rinse. On the basis of animal and human volunteer studies, it is extremely unlikely, even with misuse or excessive application, that the amount of permethrin needed to produce clinically-relevant toxic effects, would be reached. The most likely symptoms and signs following repeated, excessive application would be hypersensitivity-type reactions.

Theoretically if swallowed by a small child, alcoholic intoxication may occur due to the isopropanol content of Lyclear Crème Rinse.

Treatment

Symptomatic treatment is indicated should hypersensitivity type reactions occur.

In the event of accidental ingestion of the contents of a bottle by a child, a doctor should be consulted immediately. Gastric lavage should be considered within two hours of ingestion and management should relate to treatment of alcoholic intoxication.

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

The active ingredient, permethrin, belongs to a group of medicines called pyrethroids which are anti-parasitic agents. Permethrin is rapidly absorbed across the insect cuticle. The principle physiological lesion is the induction of electrochemical abnormalities across the membranes of excitable cells, leading to sensory hyperexcitability, incoordination and prostration. When presented in an aqueous base the ovicidal activity of permethrin is increased by the addition of an alcohol.

5.2 Pharmacokinetic properties

Absorption of permethrin across the skin is negligible. Permethrin is also very rapidly metabolised.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Isopropyl alcohol
Stearalkonium chloride
Cetyl alcohol
Ceteth-10 (polyoxyl 10 cetyl ether)
Hyetellose
Hydrolysed animal protein
Methyl parahydroxybenzoate (E218)
Balsam fir canada

Fragrance 06.070
Propyl parahydroxybenzoate (E216)
Propylene glycol
Sunset yellow (E110)
Anhydrous citric acid
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store the bottle in the outer carton.

6.5 Nature and contents of container

One or two 59ml opaque low-density polyethylene bottles closed with plastic caps with nozzle dispensers.
Included in the pack is a fine toothed comb which can be used to remove lice and eggs after treatment.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chefaro Ireland DAC,
Treasury Building,
Lower Grand Canal Street,
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1186/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5 July 1995

Date of last renewal: 5 July 2010

10 DATE OF REVISION OF THE TEXT

June 2017