

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 with known effect:

Cetyl Alcohol 2.05% w/w, Stearalkonium Chloride 3.1500 % w/w, Methyl Parahydroxybenzoate (E218) 0.2% w/w, Propyl Parahydroxybenzoate (E216) 0.08% w/w, Propylene Glycol 0.0784% w/w and Sunset Yellow (E110) 0.0016% w/w.

This medicine contains fragrance with:

Amyl cinnamal 0.005% w/w, Amylcinnamyl alcohol <0.001% w/w, Anise alcohol 0.003% w/w, Benzyl alcohol 0.289% w/w, Benzyl benzoate 0.497% w/w, Benzyl cinnamate 0.051% w/w, Benzyl salicylate 4.331% w/w, Cinnamal 0.002% w/w, Cinnamyl alcohol 0.043% w/w, Citral (neral + geranial) 0.054% w/w, Citronellol 0.289% w/w, Coumarin 0.104% w/w, Eugenol 0.522% w/w, Farnesol 0.005% w/w, Geraniol 0.443% w/w, Hexyl cinnamal 3.728% w/w, Hydroxycitronellal <0.001% w/w, Isoeugenol 0.015% w/w, Butylphenyl methylpropional <0.001% w/w, D-limonene 1.795% w/w, Linalool 1.112% w/w, Hydroxyisoethyl 3-cyclohexene carboxaldehyde <0.001% w/w, Methyl 2-octynoate <0.001% w/w, Alpha-isomethyl ionone 1.051% w/w, Evernia prunastri extract <0.001% w/w, Evernia furfuracea extract <0.001% 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.

AdultsandChildren over 6 months ofage

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 after 7-10 days of treatment with permethrin living lice are found, treatment with permethrin should be repeated. If after 14-20 days infestation is still active treatment with an alternative product should be considered.

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.

Lyclear Crème Rinse contains:

- Cetyl alcohol which may cause local skin reactions (e.g. contact dermatitis).
- Stearalkonium chloride, a type of benzalkonium chloride, which may irritate the skin.
- Methyl parahydroxybenzoate (E218), and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed). Fragrance with amyl cinnamal, amylcinnamyl alcohol, anise alcohol, benzyl alcohol, benzyl benzoate, benzyl cinnamate, benzyl salicylate, cinnamal, cinnamyl alcohol, citral (neral + geranial), citronellol, coumarin, eugenol, farnesol, geraniol, hexyl cinnamal, hydroxycitronellal, isoeugenol, butylphenyl methylpropional, D-limonene, linalool, hydroxyisohexyl 3-cyclohexene carboxaldehyde, methyl 2-octynoate, alpha-isomethyl ionone, evernia prunastri extract, evernia furfuracea extract. These allergens may cause allergic reactions.
- Benzyl alcohol which may cause mild local irritation.
- Sunset yellow which may cause allergic reactions.

Only limited experience is available with Lyclear Crème Rinse in children aged over 6 months up to 3 years. Therefore, treatment must be performed only under close specialist supervision in this age group.

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.

Treatment failure and resistance development

Varying clinical success rates to permethrin in the treatment of head lice have been observed geographically and over time. Factors associated with treatment failure include incorrect dosing or administration errors, lack of concurrent treatment of household members, and re-infestation from community contacts. Furthermore, resistance to permethrin has been detected. However, no clear correlation could be established between lack of efficacy and mutations known to confer pyrethroid resistance. Official guidance on the appropriate use of pediculicide agents should be considered.

In the case of hypersensitivity to chrysanthemums or other compositae, treatment should only be given if strictly indicated. In such cases treatment should be switched to a chemically different agent.

4.5 Interaction with other medicinal products and other forms of interactions

There are no known interactions with permethrin.

4.6 Fertility, pregnancy and lactation

Pregnancy

For precautionary reasons, the use of Lyclear Crème Rinse during pregnancy should be avoided unless physically acting treatment alternatives were ineffective and/or treatment with permethrin is required due to the woman's clinical condition.

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.

Breastfeeding

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.

Frequency not known: Paraesthesia

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 HPRC 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

Symptoms of overdose may occur in case of accidental or voluntary oral ingestion, and in rare cases of skin absorption due to excessive local application. Some symptoms that have been reported are nausea, vomiting, dizziness and convulsions.

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 06.070B (including amyl cinnamal, amylcinnamyl alcohol, anise alcohol, benzyl alcohol, benzyl benzoate, benzyl cinnamate, benzyl salicylate, cinnamal, cinnamyl alcohol, citral (neral + geranial), citronellol, coumarin, eugenol, farnesol, geraniol, hexyl cinnamal, hydroxycitronellal, isoeugenol, butylphenyl methylpropional, D-limonene, linalool, hydroxyisohexyl 3-cyclohexene carboxaldehyde, methyl 2-octynoate, alpha-isomethyl ionone, evernia prunastri extract, evernia furfuracea extract)
 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 59 ml bottles consisting of low-density polyethylene and high-density polyethylene fitted with a polypropylene disc-top cap. 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
The Sharp Building
Hogan Place
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

March 2021