

## **Package leaflet: Information for the user**

Lyclear Crème Rinse  
Cutaneous Solution  
Permethrin 1%

Kills head lice and their  
eggs

10 MINUTES

Contact time

Suitable for asthmatics

Pleasant smell

### PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Lyclear Creme Rinse carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if the symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist straight away.

#### **In this leaflet:**

1. What Lyclear Creme Rinse is and what it is used for
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#### **1. What Lyclear Creme Rinse is and what it is used for**

Lyclear Creme Rinse is used as a treatment to get rid of head lice and their eggs. It contains the ingredient permethrin which belongs to a group of medicines called pyrethroids which kill insects such as head lice.

Lyclear Creme Rinse is for use on adults and children over 6 months of age.

#### **2. Before you use Lyclear Creme Rinse**

##### **Do not use this medicine if:**

- You are allergic (hypersensitive) to any of the ingredients of Lyclear Creme Rinse (see section 6) or to other pyrethroids or pyrethrins.
- If you are known to be allergic to chrysanthemums or other compositae - you should only use Lyclear Crème Rinse after speaking to your doctor.

#### **Children up to 3 years**

Do not use Lyclear Crème Rinse in newborns and infants less than 6 months of age, unless your doctor tells you so. There is no adequate experience in infants and toddlers. Treatment to children up to 3 years of age should only be given under close medical supervision.

### **Take special care with Lyclear Creme Rinse**

If you are a healthcare worker who regularly uses Lyclear Creme Rinse on patients, you should consider wearing gloves to avoid possible irritation to your hands.

If you have asthma - Lyclear Creme Rinse may be used normally, however talk to your doctor or pharmacist before commencing treatment if you have any particular concerns.

Coloured or permed hair: There have been some extremely rare complaints about this product's effect on permed or coloured hair but it has not been studied. It is therefore a good idea to apply Lyclear to a small section of hair before treating the entire head if you colour or perm your hair.

If a child is doing their own treatment with Lyclear, it should be under adult supervision.

There is no reason to change your normal hair washing routines following treatment.

### **Taking other medicines**

Lyclear Creme Rinse is not known to interact with any medicines.

### **Pregnancy and breast feeding**

For precautionary reasons, you should not use Lyclear Crème Rinse during pregnancy unless your doctor advises you to do so.

As with all medicines, if you are breast feeding, consult your doctor before using Lyclear Creme Rinse.

### **Important Information about some of the ingredients of Lyclear Creme Rinse**

Lyclear Creme 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.

You should not apply this medicine to the breasts if you are breast feeding because the baby may take it in with your milk.

This medicine contains 46 mg propylene glycol in each 59ml bottle. This medicine contains 1859 mg Stearalkonium Chloride in each 59ml bottle.

The active ingredient of Lyclear Creme Rinse (permethrin) is not affected by chlorine in swimming pools, so normal swimming activities may continue after use.

Like other products used for the treatment of head lice, resistance can occur.





Check for head lice one week after treatment, if living lice are found, the treatment should be repeated. If after 14 days it is clear that the infestation is still active, it is recommended to use another

product with a different active.

### 3. How to use Lyclear Creme Rinse

Not to be swallowed. For external use only.

Lyclear Creme Rinse should not irritate the eyes, but it is best to avoid it coming into contact with the eyes. Rinse with plenty of cold water immediately should this happen.

<p>1. Shampoo the hair with a mild shampoo. Do not use combined shampoo-conditioner or a medicated shampoo. Rinse thoroughly and towel dry so that the hair remains damp.</p>	
<p>2. After shaking the bottle thoroughly, apply sufficient Lyclear Creme Rinse to saturate the hair, roots and scalp. Work methodically through the hair and remember to pay particular attention to the areas behind the ears and around the nape of the neck. For the majority of individuals all of the contents of this pack will be required to ensure that the hair and scalp are well saturated.</p>	
<p>3. Leave Lyclear Creme Rinse on the hair for 10 minutes. An application for longer than 10 minutes will not give better results, but a full 10 minutes is required.</p>	
<p>4. Rinse thoroughly with water. After the final rinse and while the hair is still wet, use the comb provided in the pack to remove the lice and eggs. Comb the hair in sections from the roots and work over the whole head in this way. Normal hair drying routines can then be followed.</p>	

One bottle of Lyclear Creme Rinse is usually sufficient to treat one person with shoulder length hair of average thickness, a little more may be required if the person's hair is especially thick or long. It is unlikely that 2 bottles will be required per application.

If after 7-10 days of treatment with permethrin living lice are found, treatment with permethrin should be repeated. If after 14-20 days living lice are still found, the treating physician should be consulted to consider appropriate alternative treatment options.

If one member of the family needs treatment, it is important to check the rest of the family for head lice, **but** only those infested should be treated.

#### **If you use too much**

If you accidentally apply too much Lyclear Creme Rinse, rinse thoroughly with water. If the contents of the bottle are swallowed, get medical advice from your doctor, or the Accident and Emergency Department immediately.

#### **4. Possible side effects**

Like all medicines Lyclear Creme Rinse may have some possible side-effects. Occasionally skin irritation, pruritis (itch), redness or rash may occur. However, side-effects are not common and when they occur they are usually mild and cannot always be distinguished from the head lice infestation itself. Very rarely cases of hair loss have been reported.

Frequency not known: sensations on the skin (paraesthesia) such as tingling, pricking, skin burning sensation.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +3531 6764971; Fax: +3531 6762517.

Website: <http://www.hpra.ie>; E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. Storing Lyclear Creme Rinse**

Do not store above 25°C. Keep container in the outer carton. Keep out of the reach and sight of children.

Do not use Lyclear Creme Rinse after the date (month and year) printed after "Exp" on the carton. If the expiry date has passed, take the product back to your pharmacist for safe disposal.

#### **6. Further information**

Lyclear Creme Rinse is a light orange coloured cream. Lyclear Creme Rinse is available in packs of one or two 59 ml bottles. Included in the pack is a fine toothed comb which can be used to remove lice and eggs after treatment with Lyclear.

*Active substances:* Permethrin (1 % w/w)

*Other ingredients:* Isopropyl alcohol, stearylalkonium chloride, cetyl alcohol, ceteth-10 (polyoxyl 10 cetyl ether), hyetellose, hydrolysed animal protein, methyl parahydroxybenzoate (E218), balsam fir canada, propyl parahydroxybenzoate (E216), fragrance (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), propylene glycol, sunset yellow (E110), anhydrous citric acid and purified water.

**Marketing Authorisation holder**

Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland.  
Send all enquiries to this address.

**Manufacturer**

Medgenix Benelux NV, Vliegveld 21, BE-8560 Wevelgem, Belgium.  
Date of leaflet approval: 08/2020. Lyclclear is a registered trademark.

**7. Health Guide on Head lice****Interesting facts about head lice**

It is estimated that up to half a million children catch head lice each year. Also, as with the common cold, anyone can catch head lice. So if someone in your family catches head lice, they are not alone, and it is certainly nothing to be ashamed about!

**What are head lice?**

Head lice are small insects (their size can vary depending on the stage of their development, but adults are usually between 2-3 mm long when fully grown) which vary in colour from greyish white to brown. They like to set up home in a warm head of human hair and have no preference for the type of hair, be it brunette or blonde, straight or curly, clean or dirty, head lice are not fussy.

There is only one way for head lice to pass from one individual to another and this is by head to head contact. Head lice cannot jump, hop or fly from one person to another, and it is also unlikely for them to be passed on through things like towels, combs and chair backs.

Head lice spend most of their time on or near the scalp as they need warmth to survive. They grip on to the hair by means of special claws and feed on the scalp by sucking blood.

The female louse will lay up to 8 oval shaped eggs every night, gluing them to the base of individual hairs. After about seven days a young louse (nymph) emerges, leaving behind it a white egg shell. These white egg shells remain glued to the hair and are known as nits. The nymph will begin feeding in the same way as the adult and within about 10 days will be mature and capable of breeding.

**What to look for**

Due to their size, colour and rapid movement, head lice are difficult to see. The eggs (creamy brown) are a little easier to spot and will be found attached to individual hairs near to the scalp. In contrast, the white nits can often be seen further from the scalp, this is because as the hair grows, the nits (which are still glued to the hair shaft) move with it.

The best way to find head lice and their eggs is to run a fine-toothed comb through damp parted hair looking carefully for evidence of lice. Signs to look for include faeces, cast skins or dead lice.

Louse faeces appear as black flecks like dust, often this is rubbed onto collars or the pillow at night resulting in shirts and bed clothes becoming dirty more quickly than usual.

**How to prevent head lice**

Steps that can be taken to reduce the possibility of an infection include:

- a) Check whole family's hair using a fine toothed detection comb on a regular basis, for any signs of head lice. If live head lice are found it is important to trace the source of the original infection. This may be someone well known to the family, but who may not be aware that they have head lice. If this person is not identified and treated, others can be quickly infected, sometimes within hours after treatment.
- b) If a child in your family is found to have lice, please inform their school, other parents, Health Visitor and School Nurse.

### **Getting the best from this treatment**

In most cases a single treatment is sufficient to eliminate head lice. Use of hair mousses, gels, sprays, 2 in 1 shampoos and conditioners immediately before treatment may reduce its effectiveness.

Lice may continue to move or twitch up to 24 hours after treatment, this is normal and not a sign of treatment failure.

There is potential for head lice to develop resistance to treatments. If you detect live lice during the 7 days after the first application, a second treatment should be given on day 7. If further treatments are required consult a doctor or pharmacist, continual repetitive treatment should be avoided.