

FINAL ARTWORK

02/280 Lyclear Creme Rinse

All PIL Ireland

Date:28/04/08

COLOURS:

PMS
151

PMS
293

Cutter

Black

PMS

PMS

SIZE:

210 x 157 MM

Lyclear

CREME RINSE

Cutaneous Solution
1% PERMETHRIN
EFFECTIVE AGAINST HEAD LICE

10
MINUTE TREATMENT
Suitable For Asthmatics

PATIENT INFORMATION LEAFLET

Lyclear is a trade mark

Please read this leaflet carefully before you start to use Lyclear Creme Rinse because it contains important information about your treatment. This medicine is available without prescription so that you can treat a mild illness without a doctor's help. However, you will still need to use Lyclear Creme Rinse carefully to get the best results from it.

- Keep this leaflet, you may want to read it again.
- Ask your doctor or pharmacist if you have any questions or are not sure about anything.
- Usually a single application clears the infection. If you are in doubt about the success of the treatment talk to your doctor.

What Lyclear Creme Rinse is and what it is used for

Lyclear Creme Rinse is a light orange coloured cream (cutaneous solution). The cream contains the active ingredient Permethrin 1% w/w. It also contains 20% w/w isopropyl alcohol, steralkonium chloride, cetyl alcohol, ceteth-10 (polyoxyl 10 cetyl ether), hyetellose, hydrolysed animal protein, methyl parahydroxybenzoate (E218), balsam fir canada, propyl parahydroxybenzoate (E216), fragrance 06.070, propylene glycol, sunset yellow (E110), anhydrous citric acid and purified water. 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.

Lyclear Creme Rinse is used to treat head louse infections. Permethrin (the active ingredient) belongs to a group of medicines called pyrethroids which are anti-parasitic agents.

The Product Authorisation holder is Chefaro UK Ltd., 3 Percy Road, Huntingdon, Cambs, PE29 6SZ.

The Manufacturer is Omega Teknika Ltd., Farnham Drive, Finglas, Dublin 11, Ireland.

Before using Lyclear Creme Rinse

Lyclear Creme Rinse is suitable for most people, but a few people should not use it. If you are in any doubt you should contact your doctor or pharmacist.

DO NOT USE LYCLEAR CREME RINSE IF:

You have ever had a reaction to Lyclear Creme Rinse, pyrethroids, pyrethrins or to any of the ingredients listed above.

TAKE SPECIAL CARE WITH LYCLEAR CREME RINSE IF:

- You are nursing staff who routinely uses Lyclear Creme Rinse as you may wish to wear gloves to avoid possible irritation to the hands.
- You are asthmatic – Lyclear Creme Rinse may be used as normal in asthmatics, however talk to your doctor or pharmacist before commencing treatment if you have any particular concerns.

If you are treating children Lyclear Creme Rinse is for external use only and is only suitable for use in adults and children over 6 months of age. Children should be supervised during use. The use of Lyclear Creme Rinse in children below the age of 6 months should only be on the advice of a doctor.

Lyclear Creme Rinse should not irritate your eyes, although care should be taken when applying. If accidental contact does occur, rinse immediately with plenty of water.

The effect of this product on artificial hair colourants and perms has not formally been studied, although complaints are extremely rare. It is good practice to apply to a small section of hair first, before treating the entire scalp.

The active ingredient of Lyclear Creme Rinse (permethrin) is unaffected by chlorine in swimming pools, so normal swimming activities may continue after use. There is no reason to change your normal hair washing routines following treatment.

PREGNANCY AND BREAST-FEEDING

Ask your doctor or pharmacist for advice before using Lyclear Creme Rinse if you are pregnant or breast-feeding.

IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS IN LYCLEAR CREME RINSE:

Lyclear Creme Rinse contains methyl and propyl parahydroxybenzoate (E218 and E216), which may cause skin reaction such as contact dermatitis and more rarely wheezing.

Propylene glycol and cetyl alcohol may cause skin irritations such as contact dermatitis. Sunset Yellow (E110) may cause allergic reactions including asthma. Allergy is more common in those who are allergic to aspirin.

How to use Lyclear Creme Rinse:

Lyclear Creme Rinse is for external use only.

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 more than 2 bottles will be required per application.

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

PLEASE FOLLOW THESE INSTRUCTIONS CAREFULLY:
SEE OVERLEAF.

How to use Lyclear Creme Rinse:

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.



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.

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.



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.

Lyclear Creme Rinse should not irritate your eyes, although care should be taken when applying. If accidental contact does occur, rinse immediately with plenty of water.

What if I use too much Lyclear Creme Rinse

If you accidentally apply too much Lyclear Creme Rinse, rinse thoroughly with water.

What if Lyclear Creme Rinse is swallowed

If Lyclear Creme Rinse is accidentally swallowed, tell your doctor at once. If you cannot do this, go to the nearest hospital accident and emergency (casualty) department. Take along any product that is left, the bottle and the label so that the hospital can tell what product you have used.

Possible side-effects

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

If you notice any side-effects not mentioned in this leaflet, or are worried about the above side-effects, contact your doctor or pharmacist.

Storing Lyclear Creme Rinse

- Do not store above 25°C. Keep container in the outer carton.
- Remember, as with all medicines, keep Lyclear Creme Rinse out of the reach and sight of children.
- Do not use after the last day of the month shown on the expiry date on the carton and bottle.

Return any out of date medicine to your pharmacist.

For any further information you should contact your doctor or pharmacist.

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HEALTH GUIDE

FURTHER INFORMATION

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:

- 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.
- 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.