

Lyclear® Dermal Cream

Permethrin

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 Dermal Cream 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 straightaway.

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1. What Lyclear Dermal Cream is and what it is used for

Lyclear Dermal Cream is used to treat infestations of scabies and crab lice on the body. It contains the ingredient permethrin which belongs to a group of medicines called pyrethroids which kill mites such as scabies and crab lice.

2. Before you use Lyclear Dermal Cream

Do not use Lyclear Dermal Cream:

- If you are allergic to Permethrin, other pyrethrins or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Lyclear Dermal Cream:

- If you are treating infants – see below in the section “Children up to 23 months of age”.
- If you are known to be allergic to chrysanthemums or other compositae - you should only use Lyclear Dermal Cream after speaking to your doctor.

Warning

For cutaneous use only! Do not swallow this medicine.

Avoid contact with eyes or mucous membranes (inside the nose or throat, genital region) or open wounds.

Lyclear Dermal Cream may worsen symptoms of asthma or eczema.

Children up to 23 months of age

Do not use Lyclear Dermal Cream in newborns and infants less than 2 months of age, unless your doctor tells you so. There is no adequate experience in infants and toddlers. Treatment to children up to 23 months of age should only be given under close medical supervision.

Taking other medicines

Corticosteroids (steroids) should not be used to treat skin conditions like eczema when Lyclear Dermal Cream is being used because they may make the infestation of scabies and lice worse by interfering with the body's natural defence to scabies and crab lice.

Lyclear Dermal Cream is not known to interact with any medicines.

Pregnancy and breast feeding

As with all medicines, if you are pregnant or breast feeding, consult your doctor before using Lyclear Dermal Cream during pregnancy or while breast feeding.

Important information about some of the ingredients of Lyclear Dermal Cream

Lyclear Dermal Cream contains butylated hydroxytoluene (E321) and formaldehyde which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes (lining of the nose, mouth and genital areas).

Lyclear Dermal Cream contains paraffins. These excipients of the cream can reduce the efficiency and hence the reliability of latex products (e. g. condoms, diaphragms) used at the same time.

Lyclear Dermal Cream is harmful to all types of insects and also to animals living in water e. g. fish. Take care that Lyclear Dermal Cream does not get into aquaria or terraria.

3. How to use Lyclear Dermal Cream

Always use Lyclear Dermal Cream exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. To pierce tube, remove the cap and reverse it over the nozzle, push firmly and turn.

Apply the cream to clean, dry, cool skin. Do not take a hot bath or shower immediately before treatment.

Carefully apply a thin layer of cream to the skin (see “How and when should you use Lyclear Dermal Cream?”).

To treat scabies

Adults and adolescents over 12 years of age. Apply up to 30 g of cream (corresponding to one tube of 30 g)

Children aged from 6 - 12 years. Apply up to 15 g of cream (corresponding to ½ tube of 30 g)

Children aged from 2 months - 5 years. Apply up to 7.5 g of cream (corresponding to ¼ tube of 30 g)

Newborns and infants under 2 months of age. There is only limited amount of data available in this age group and no dose can be recommended (see also section 2 under “warnings and precautions”).

The above information is merely a guide. The dose can be adjusted according to the needs of the individual patient and the individual body surface area. For example, some adults require a larger amount of cream.

To treat crab lice

Adults over 18 years of age: Apply up to 30 g of cream (corresponding to one tube of 30 g).

How and when should you use Lyclear Dermal Cream?

Lyclear Dermal Cream is for cutaneous use only.

Take care not to allow the cream to get into the eyes or come into contact with mucous membranes (inside the nose or throat, genital region) or open wounds. If accidental contact occurs, rinse thoroughly with water.

Adults should apply the cream to the whole body including the neck, palms of the hands and soles of the feet. The head and face can be spared unless this area includes places affected by scabies (itch mites).

When applying the cream, the areas between the fingers and toes (also under the finger- and toe-nails), the wrists, elbows, armpits, external genitalia and buttocks should be especially carefully treated.

For treatment of crab lice in adults: Any facial hair (beards moustaches) and eyelashes should be checked for the presence of live lice and eggs. Cream should be applied to any facial hair, carefully avoiding eyes. If live lice or eggs are found on the eyelashes they should be removed carefully using tweezers. Cream should not be applied to the eye lashes because the cream can cause moderate eye irritation.

Children. Children should apply the cream uniformly to the whole body, including the palms of the hands, soles of the feet, neck, face, ears, and scalp. Parts of the skin around the mouth (because the cream could be licked off) and the eyes should be spared. Keep your child from licking the cream from the hands. If necessary, children should wear gloves.

There is no adequate experience in infants and toddlers. Treatment to children up to the age of 23 months should therefore only be treated under close medical supervision.

Elderly. Elderly patients (over 65 years) should use the cream in the same way as adults but in addition, the face, ears and scalp should also be treated. Care should be taken to avoid applying the cream to areas of skin around the eyes.

How long should you use Lyclear Dermal Cream?

One application of Lyclear Dermal Cream is usually sufficient.

Leave the cream on the skin for at least eight hours, for example, overnight. Avoid bathing, showering or washing during this period, because this could endanger the success of treatment. If, by way of an exception, you have to wash your hands within the eight hour period, then reapply the cream to the hands and wrist area. The same applies if you have to wash other parts of treated skin (buttocks, external genitalia).

After at least eight hours, take a shower or wash the skin with soap and water.

Provided these instructions for use are followed, a single application is generally sufficient for successful treatment. However, in cases of persistent or renewed infestation, it may be necessary to repeat the treatment after 14 days.

If you use too much:

If too much cream is applied, it should be washed off with soap and warm water. If there are any signs of irritation, talk to your doctor. If the contents of the tube are swallowed by a child get medical aid from the doctor or Accident and Emergency Department of the nearest hospital immediately.

4. Possible side effects

Like all medicines, Lyclear Dermal Cream can cause side effects, although not everybody gets them.

If severe hypersensitivity reactions occur, please consult a doctor immediately! In this case you must not use Lyclear Dermal Cream any more.

Common: may affect up to 1 in 10 people.

Itching (pruritus), reddening of the skin or unusual sensations on the skin (paraesthesias) such as tingling, pricking, skin burning sensation as well as dry skin are common. However, such symptoms can also occur as a result of the disease itself. Moisturisers and oil baths are recommended as follow up treatment for dry skin. The itching and a skin rash (post-scabies eczema) may persist for up to four weeks after the end of treatment. This is caused by a reaction to the killed scabies mites. If after using Lyclear Dermal Cream you have the impression that the disease is persisting, please speak to your doctor before applying it again.

Rare: may affect up to 1 in 1,000 people.

Headache can occur rarely.

Very rare: may affect up to 1 in 10,000 people.

Very rarely, skin lesions (excoriations), inflammation of the hair follicles (folliculitis) and reduced skin pigmentation have been reported at the time Lyclear Dermal Cream is used.

Sensitive/allergic persons have reported breathing difficulties at the time substances from the pyrethrin group were being used.

Not known: frequency cannot be estimated from the available data.

Intolerability reactions may occur on the skin (contact allergy reactions) that are expressed as itching, reddening, blisters or nettle rash (urticaria). These reactions may also spread beyond the area of skin treated.

Nausea may appear. Vomiting was not reported after the use of Lyclear Dermal Cream but is known in connection with other permethrin-containing drugs.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. Storing Lyclear Dermal Cream

Do not store above 25°C. Do not freeze. Keep out of the reach and sight of children. Do not use Lyclear Dermal Cream after the date 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 Dermal Cream is a white cream in a 30 g tube. Active substances: Permethrin (5% w/w)

Other ingredients: Coconut oil, glyceryl monostearate, macrogol cetyl ether, cetomacrogol 1000, isopropyl myristate, lanolin alcohols/liquid paraffin mixture, butylated hydroxytoluene (E321), glycerol, formaldehyde solution, carbomer, sodium hydroxide and purified water.

Marketing Authorisation holder: Omega Pharma Ltd., 1st Floor, 32 Vauxhall Bridge Road, London, SW1V 2SA, United Kingdom. Send all enquiries to this address.

Manufacturer: Medgenix Benelux NV, Vliegveld 21, BE-8560 Wevelgem, Belgium.

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