

Package leaflet: Information for the user
Lyclear® 5% w/w Dermal Cream
Permethrin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse

What is in this leaflet:

1. What Lyclear Dermal Cream is and what it is used for
2. What you need to know before you use Lyclear Dermal Cream
3. How to use Lyclear Dermal Cream
4. Possible side effects
5. How to store Lyclear Dermal Cream
6. Contents of the pack and other information

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

Lyclear 5% w/w Dermal Cream belongs to a group of medicines called pyrethroids, which are anti-parasitic agents.

Lyclear Dermal Cream is used to treat scabies and crab louse infections.

2. What you need to know 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.
- Lyclear Dermal Cream is for cutaneous use only. Do not swallow this medicine.
- Avoid contact with the eyes or mucous membranes (inside the nose or throat, genital region) or open wounds. In the event of eye contamination, rinse immediately with water or normal saline if readily available.
- Individuals routinely involved in treating others may wish to wear gloves to avoid any possible irritation to the hands.

Stop using Lyclear Dermal Cream if you experience skin irritation and consult a doctor if it doesn't improve.

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 of children up to 23 months of age should only be given under close medical supervision

Other medicines and Lyclear Dermal Cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are currently using a type of medicine called a corticosteroid, you should speak to your doctor or pharmacist before you use this medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Lyclear is not known to affect your ability to drive or use machines

Lyclear Dermal Cream contains formaldehyde and butylhydroxytoluene (E321)

These may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

Lyclear Dermal Cream also contains liquid paraffin.

This excipient of the cream can reduce the efficiency and hence the reliability of latex products (e.g. condoms, diaphragms) used at the same time.

3. How to use Lyclear Dermal Cream

Always use this medicine exactly as described in this leaflet or as your doctor/pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Ensure the skin is clean, dry and cool.
- If you take a warm bath prior to treatment, the skin should be allowed to cool before the cream is applied.
- Carefully apply a thin layer of the cream to the skin (see "How and when should you use Lyclear Dermal Cream?")
- The cream rubs easily into the skin. It is not necessary to apply more cream until you can see it on the surface.
- Usually a single application clears the infection. If you are in doubt about the success of treatment, consult your doctor.
- Lyclear is not suitable for use in babies under 2 months of age.

Treatment of scabies:**Adults and adolescents over 12 years of age:**

Apply up to 30 g of cream (corresponding to one tube)

Children aged from 6 to 12 years:

Apply up to 15 g of cream (corresponding to half of a tube)

Children aged from 2 months to 5 years:

Apply up to 7.5 g of cream (corresponding to a quarter of a tube)

Newborns and infants under 2 months:

There is only limited 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. A few adults may need to use an additional tube, but do not apply more than two tubes.

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 area 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.

In women, cream should also be applied to the breasts.

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 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 8 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.

Treatment of Crab Lice:

Use in adults and children over 2 months, and the elderly:

- It is recommended that up to one-third of a 30 g tube should be sufficient to treat the pubic region, perianal region, thighs and trunk. A few adults may need to use more cream to ensure a complete treatment, but not more than two-thirds of a tube should be used.
- For children and relatively hair-free individuals proportionately less cream will be required.
- Sufficient cream should be applied to cover the pubic region, the area around the anus, inner thighs down to the knees and any hair on the trunk, which extends to the pubic area.
- Any facial hair, except the eyelashes and eyebrows should also be treated if found to be infested with lice or their eggs.
- Since the dermal cream may cause marked eye irritation, it is recommended that any lice or eggs found in the eyelashes should be removed with a pair of tweezers. Lyclear Dermal Cream should not be applied to this area.
- It is unusual for crab lice to infest the eyebrows. Lice or eggs found in this area are more likely to be head lice and therefore care should be taken when making a diagnosis. Ask your pharmacist for advice.
- The cream should be left on for at least 8 hours, then washed off with soap and water not more than 24 hours later.
- A second treatment should be administered if live lice are found on previously treated area 7 days after treatment.

The dosage recommendations given in this leaflet are only intended as a guide to treatment. Because individuals can vary so much in size you might find that you need to apply slightly more or slightly less cream to completely cover the body. This will not harm you or reduce the effectiveness of the treatment.

For children less than 18 years of age seek medical advice before using the product.

Patients over 70 years should be treated under medical supervision.

Your direct contacts should also be treated. Ask your pharmacist for advice.

What to do if the cream is accidentally swallowed

If the contents of the tube are accidentally swallowed, you should consult a doctor or go to the nearest hospital emergency department as soon as possible. Take the tube with you to show which medicine has been swallowed.

If you use more Lyclear Dermal Cream than you should

If excessive cream is applied it should be washed off with soap and warm water. If there are any signs of irritation a doctor should be consulted.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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 (paraesthesia) such as tingling, prickling, 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 bath oils are recommended as follow up treatment for dry skin. The itching and a skin rash (post-scabies eczema) may persist for up to 4 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.

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):

Nettle rash which may spread beyond the area of skin treated.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lyclear Dermal Cream

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the tube and carton. The expiry date refers to the last day of that month.
- Do not store above 25° C. Do not freeze.
- Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lyclear Dermal Cream contains

- The active substance is permethrin (5% w/w equivalent to 50 mg/g).
- The other ingredients are triglycerides (medium chain), glycerol monostearate 90%, macrogol (2) cetyl ether, glycerol, isopropyl myristate, liquid paraffin, wool alcohols, cetomacrogol 1000, carbomer 974P-NF, formaldehyde solution (see section 2), butylhydroxytoluene (E321) (see section 2), sodium hydroxide and purified water.

What Lyclear Dermal Cream looks like and contents of the pack

Lyclear Dermal Cream is a white to off white cream and comes in tubes containing 30 g of cream.

Marketing Authorisation Holder

GlaxoSmithKline (Ireland) Ltd.
12 Riverwalk
Citywest Business Campus
Dublin 24

Manufacturer

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This leaflet was last revised in July 2015.

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