

**Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) – 1986**

The medicine is dispensed according to a physician's prescription only

Lyclear Dermal Cream

The tube contains Permethrin 5% w/w.

List of the additional ingredients is detailed in section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is not intended for babies under the age of 2 months old.

1. What is the medicine intended for?

Lyclear Dermal Cream is used to treat scabies.

Therapeutic group: Lyclear Dermal Cream belongs to a group of medicines called pyrethroids, which are anti-parasitic agents.

2. Before using the medicine

Do not use the medicine if:

- you are sensitive (allergic) to permethrin, other pyrethrins, to any of the additional ingredients contained in the medicine (listed in section 6) or to chrysanthemums.

Special warnings regarding the use of the medicine

Talk to your physician 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 plants from the compositae family, you should only use Lyclear Dermal Cream after talking to your physician.
- Lyclear Dermal Cream is intended 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 contact, rinse immediately with water or saline (salt solution 0.9%, if readily available).
- People 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 physician if it does not 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 physician 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

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist. Especially inform the physician or the pharmacist if you are currently taking a type of medicine called a corticosteroid 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, consult the physician or the pharmacist before using this medicine.

Driving and using machines

Lyclear Dermal Cream is not known to affect your ability to drive or operate machines.

Important information about some ingredients of the medicine

Lyclear Dermal Cream contains formaldehyde, which may cause a local skin reaction (e.g. contact dermatitis).

Lyclear Dermal Cream contains butylated hydroxytoluene, which may cause a local skin reaction (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Lyclear Dermal Cream also contains liquid paraffin.

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

3. How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.

- Ensure the skin is clean, dry and cool.
- If you take a warm bath prior to treatment, you should allow the skin 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 physician.
- Lyclear Dermal Cream is not suitable for use in babies under 2 months of age.
- Older children should be supervised by an adult when applying the cream.

The dosage and treatment will be determined only by the physician. The usual dosage is:

| | |
|---|---------------------------|
| Adults and children over 12 years: | Up to one tube |
| Children: 6 to 12 years: | Up to half of a tube |
| 1 to 5 years: | Up to a quarter of a tube |
| 2 months to 1 year: | Up to an eighth of a tube |

Newborns and infants under 2 months of age:

There is only limited data available in this age group and no dosage can be recommended (see also section 2 under "Special warnings regarding the use of the medicine").

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, the cream should also be applied to the breasts.

After applying the cream, put clean clothes on.

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 of 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 7 days.

Do not exceed the recommended dose

For external use only

What to do if the cream is accidentally swallowed

If a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you accidentally have taken a higher dosage

If you use more than you should, wash the excess cream with soap and warm water. If there are any signs of irritation, consult a physician.

Persist with the treatment as recommended by the physician.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, use of Lyclear Dermal Cream may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

If severe hypersensitivity reactions occur, please consult a physician 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 side effects. 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 talk to your physician before applying the cream again.

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

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.

If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 25°C. Do not freeze.
- Use within 6 months after first opening, but not past the expiry date.
- Do not throw away any medicine into the wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This will help protect the environment.

6. Additional information

- In addition to the active ingredient the medicine also contains – Triglycerides (medium chain), glyceryl monostearate, macrogol (2) cetyl ether, glycerol, isopropyl myristate, cetomacrogol 1000, wool alcohols, formaldehyde solution (see section 2), liquid paraffin (see section 2), carbomer 974P, butylated hydroxytoluene (E321) (see section 2), sodium hydroxide and purified water.
- What does the medicine look like and what is the content of the package –

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

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 060-18-27015

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