

# 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.

### In this leaflet:

- |   |                                 |
|---|---------------------------------|
| 1. What Lyclear Dermal Cream is and what it is used for | 4. Possible side effects        |
| 2. Before you use Lyclear Dermal Cream                  | 5. Storing Lyclear Dermal Cream |
| 3. How to use Lyclear Dermal Cream                      | 6. Further information          |

### 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 this medicine if:

- you are allergic (hypersensitive) to any of the ingredients of Lyclear Dermal Cream (see section 6)

#### 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).

### 3. How to use Lyclear Dermal Cream

Not to be swallowed. For external use only. Avoid contact with the eyes. Rinse with plenty of cold water immediately should the cream accidentally get into the eyes.

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.

The cream rubs completely into the skin so you do not need to keep applying more cream until you can see it on the skin.

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.

#### To treat scabies

The cream should be left on for at least 8 hours and washed off with soap and water within 12 hours.

Re-apply Lyclear Dermal Cream to hands if they are washed with soap and water within 8 hours of treatment.

Usually a single application clears the infestation. If you are in doubt about the success of treatment, talk to your doctor or pharmacist.

**Adults and children over 2 years:** apply Lyclear Dermal Cream to the whole body but **not** the head and face. Pay special attention to the areas between the fingers and toes (including under the nails), wrists, armpits, external genitalia, breasts and buttocks.

**Elderly (over 65 years old):** apply as directed for adults but also include necks, faces, ears and scalps. Avoid the area around the eyes.

**Babies and children under 2 years old:** apply as for adults but also apply to their necks, faces, ears and scalps. Avoid the area around the eyes and the mouth as the cream could be licked off.

*Children between 2 months and 2 years should only be treated under medical supervision.*

The table shows how much cream should normally be used:

AGE	DOSAGE
Adults, elderly and children over 12 years	Up to one tube. A few adults may need to use an additional tube, but do not apply more than two tubes.
Children aged 6 to 12 years	Up to half a tube
Children aged 1 to 5 years	Up to a quarter of a tube
Babies aged 2 months to 1 year	Up to an eighth of a tube

#### To treat crab lice

**Not** recommended for persons under 18 years of age.

Elderly people should only be treated under medical supervision.

**Adults 18 years and over:** Sufficient cream should be applied to cover the pubic region, peri-anal (around the anus), inner thighs down to the knees and any hair that grows up from the pubic area to the chest/stomach.

One (30 g) tube is more than sufficient to treat one hairy adult. It is recommended that up to a third of a tube is used to treat the pubic region, around the anus, thighs, stomach and chest. Not more than two thirds of the tube should be needed for complete treatment.

For relatively hair-free individuals less cream will be required.

The cream should be left on for 24 hours and then washed off with soap and water.

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.

**Adults 18 years and over:** Sufficient cream should be applied to cover the pubic region, peri-anal (around the anus), inner thighs down to the knees and any hair that grows up from the pubic area to the chest/stomach.

One (30 g) tube is more than sufficient to treat one hairy adult. It is recommended that up to a third of a tube is used to treat the pubic region, around the anus, thighs, stomach and chest. Not more than two thirds of the tube should be needed for complete treatment.

For relatively hair-free individuals less cream will be required.

The cream should be left on for 24 hours and then washed off with soap and water.

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.

#### 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 these are rare and usually mild.

- Occasionally burning or stinging of the skin occurs, but this is usually slight and passes quickly.
- Treatment of scabies may result in continued or increased irritation for a short while. This may show as redness of the skin, a rash or itching.
- You might find that the itching you have been experiencing with scabies continues for up to 4 weeks after treatment with Lyclear Dermal Cream. This is normal and is caused by an allergic reaction to the dead scabies mites. It is not a sign that the treatment has failed.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### 5. Storing Lyclear Dermal Cream

Do not store above 25°C. Do not freeze. Do not dilute. Keep out of the reach and sight of children. Do not use Lyclear Dermal Cream 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 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:** Stiefel Laboratories (Ireland) Ltd., Finisklin Business Park, Sligo, Ireland or Medgenix Benelux NV, Vliegveld 21, BE-8560 Wevelgem, Belgium.

Lyclear is a registered trademark. Date of leaflet approval: November 2012. LYD01841112v1

25921.01  
P1 7161 04