

Package leaflet: information for the patient

Permethrin InfectoPharm, 50 mg/g, cream
Permethrin (25:75)

Read the entire 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, pharmacist, or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your pharmacist.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.
- Is your complaint not getting better, or is it even getting worse? Then contact your doctor.

Contents of this leaflet

1. What is Permethrin InfectoPharm and what is it used for?
 2. When should you not use this medicine or be extra careful with it?
 3. How to use this medicine?
 4. Possible side effects
 5. How to store this medicine?
 6. Contents of the packaging and other information
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1. What is Permethrin InfectoPharm and what is it used for?

The active substance in Permethrin InfectoPharm is permethrin.

Permethrin belongs to a group of medicines called pyrethroids. These are antiparasitic medicines. This medicine is used for the treatment of scabies (itch mite) in adults, adolescents, and children at least 2 months old. Scabies is a skin disease.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to permethrin, other pyrethrins, or any of the other ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

- Are you treating babies? Then read the section "Children up to and including 23 months of age".
- If you have a known allergy to chrysanthemums or other plant species from the plant family called Asteraceae (Compositae) - you may only use this medicine after consulting your doctor.

Warning

For external use only (cutaneous)! Do not ingest this medicine.

The cream can cause irritation to the conjunctiva of the eye. Ensure that this medicine does not come into contact with the eyes or mucous membranes (in the nose or throat, or in the penis or vagina), or with open wounds. If this happens, rinse the area immediately with water.

Healthcare workers using permethrin are advised to wear gloves.

This medicine is harmful to all types of insects and cats. It is also harmful to aquatic animals, such as fish. Ensure that this medicine does not come into contact with these animals. Also, ensure that this medicine does not enter a fishbowl (aquarium) or a container with insects or reptiles (terrarium).

This medicine can worsen the symptoms of asthma or eczema.

Children up to and including 23 months of age

Do not use this medicine in newborns and babies younger than 2 months, unless your doctor advises it. There is not enough experience with babies and toddlers. Treatment should only be given to children up to and including 23 months under close medical supervision.

Are you using any other medicines?

Are you using any other medicines besides Permethrin InfectoPharm, have you recently done so, or are you planning to do so soon? Then tell your doctor or pharmacist.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine.

Some data on the use of permethrin in pregnant women indicate that it is not harmful. For safety, it is preferable not to use this medicine during pregnancy. Do so only if your doctor advises it.

Permethrin, the active substance in this medicine, can enter breast milk. For safety, you should not breastfeed for five days after using this medicine.

Permethrin InfectoPharm contains paraffins

Are you using latex products (such as condoms, diaphragms) at the same time as this medicine? The excipients in the cream can cause latex products to work less effectively. As a result, latex products may be less reliable.

Permethrin InfectoPharm contains cetostearyl alcohol and sorbic acid

Cetostearyl alcohol and sorbic acid can cause skin reactions at that site (such as an itchy rash on the skin (contact dermatitis)).

3. How do you use this medicine?

Always use this medicine exactly as your doctor has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Carefully apply a thin layer of cream to the skin (see “How and when do you use this medicine?”)

Adults and adolescents over 12 years

Apply up to 30 g of cream (is the same as 1 tube of 30 g or ½ tube of 60 g)

Children from 6 to 12 years

Apply up to 15 g of cream (is the same as ½ tube of 30 g or ¼ tube of 60 g)

Children from 2 months to 5 years

Apply up to 7.5 g of cream (is the same as ¼ tube of 30 g or ⅛ tube of 60 g)

Newborns and infants under 2 months

There is little data available in this age group and no dose can be advised (see also “Warnings and precautions”).

The explanation above is an estimate. The dose can be adjusted. This depends on how much the patient needs and the size of the body. For example, some adults may need more cream. If the face, ears, or scalp are treated, more cream may be used.

How and when do you use this medicine?

This medicine is for use on the skin only (cutaneous).

Make sure the cream does not get into your eyes. Also, do not let it come into contact with mucous membranes (in the nose or throat, or in the penis or vagina) or with open wounds. If this happens accidentally, rinse well with water.

Adults should apply the cream to the entire body, including the neck, the insides of the hands, and under the feet. The head and face do not need to be treated, except if these areas are affected by scabies (itch mites). When using the cream, ensure that the areas between the fingers and toes (also under the fingernails and toenails), the wrists, elbows, armpits, the area outside the penis or vagina, and the buttocks are well covered.

Children

Children should apply the cream thoroughly over the entire body. This includes the insides of the hands, under the feet, the neck, face, ears, and scalp. Areas of skin around the mouth (as the cream can be licked off) and the eyes should be left untreated.

Ensure that your child does not lick the cream off their hands. If necessary, children should wear gloves. There is not enough experience with this medication in babies and toddlers. Treatment of children up to 23 months should therefore only occur under the supervision of a healthcare professional.

Elderly

Older patients (over 65 years) should use the cream in the same way as adults. Additionally, the face, ears, and scalp should also be treated. Ensure that the cream is not applied to the skin around the eyes.

How long should you use this medication?

Usually, it is sufficient to use this medication once.

Leave the cream on the skin for 8 to 14 hours, for example, while you sleep. Do not bathe, shower, or wash yourself during this period. This is not allowed because the treatment may not work. Do you need to wash your hands during this period? Reapply the cream to your hands and wrists. This also applies if you need to wash other treated areas of the skin (buttocks, the outside of the penis or vagina).

After 8 to 14 hours, take a shower or wash your skin with water and soap.

If this instruction is followed, it is usually sufficient to use this medication once for effective treatment. Sometimes, an infestation may not completely clear or may return. Consider another treatment 7 to 14 days after the first treatment.

What else should you pay attention to?

Everyone who comes into contact with you should visit a doctor as soon as possible. This is especially true for your family members and partners. The doctor will decide if these individuals also need treatment.

Are infected individuals you have been in contact with not treated quickly enough? Then it is possible that they may reinfect you with scabies.

You should also

- keep your fingernails short and clean
- change clothing, bedding, and towels daily for 4 days. Wash them at a temperature of at least 60 °C
- store items that cannot be washed at a temperature of at least 60 °C (such as outerwear) in a sealed plastic bag for a few days
- vacuum carpets and upholstered furniture thoroughly

Do you think this medicine works too strongly or too weakly? Then contact your doctor or pharmacist.

Have you used too much of this medicine?

Do not worry about overdose if you apply this medicine to the outside of your body.

Did you accidentally or intentionally swallow the cream? Then contact a doctor as soon as possible. The doctor will decide what needs to be done.

Did you forget to use this medicine?

Use the cream as soon as possible if you have forgotten it.

If you stop using this medicine

Usually, it is enough to use this medicine once. Has your doctor advised you to use the cream again? Then follow the doctor's instructions. Otherwise, you may not fully recover.

Do you have any other questions about using this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can have side effects. Not everyone experiences them.

Contact a doctor immediately in case of severe hypersensitivity reactions! You should no longer use this medicine.

Common (occur in less than 1 in 10 users)

Itching (pruritus), red skin, or skin sensations (paresthesia) such as tingling, prickling, or burning sensation of the skin. These complaints can also occur due to the disease itself.

Moisturizing creams and bath oil are recommended as follow-up treatment for dry skin. The itching and skin rash (eczema after scabies) can persist up to four weeks after the end of treatment. This is due to a reaction to the killed scabies mites. Do you think you are still infected after using this medicine? Then contact your doctor before using this medicine again.

Rare (occur in less than 1 in 1,000 users) Headache occurs rarely.

Very rare (occur in less than 1 in 10,000 users)

Very rarely, skin lesions (excoriations), inflammation of the hair follicles (folliculitis), and lightening of the skin have been reported when this medicine was used.

Sensitive/allergic individuals have reported difficulty breathing when substances from the pyrethrin group were used.

Not known (cannot be determined from the available data)

It is possible that you may experience allergic reactions on the skin (contact allergy reactions). These include symptoms such as itching, red skin, blisters, or hives (urticaria). These reactions can also spread beyond the treated area of the skin. You may also feel nauseous. Vomiting has not been reported after using this medication. However, it is a known side effect of other medications containing permethrin.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you help us gather more information about the safety of this medication.

5. How to store this medication?

Keep out of the sight and reach of children.

Do not use this medication after the expiry date. You can find this on the tube and the outer packaging after EXP. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medication.

This medication must be used within three months after first opening the tube.

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medications you no longer use. Proper disposal of medications ensures they are destroyed correctly and do not enter the environment.

Permethrin is very toxic to animals living in water, soil, and on the ground. Therefore, it is important that this medication does not come into contact with fish tanks (aquariums) and

containers where insects and reptiles live (terrariums). Also ensure that this medication does not come into contact (even when on the skin) with invertebrate animals, especially insects.

6. Contents of the packaging and other information What substances are in this medication?
- The active substance in this medication is permethrin.
1 g cream contains 50 mg permethrin (25:75).
 - The other substances in this medication are cetostearyl alcohol (type A), emulsifier, liquid paraffin, white soft paraffin, sorbic acid, and purified water.

What does Permethrin InfectoPharm look like and what is in a package?

Permethrin InfectoPharm is a soft, white cream.

Permethrin InfectoPharm is available in packages of 30 g and 60 g cream.

It is possible that not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

INFECTOPHARM Arzneimittel und Consilium GmbH Von-Humboldt-Strasse 1
64646 Heppenheim Germany

For all information regarding this medicine, contact your doctor or pharmacist (and nurse). If desired, you can also contact the local representative of the marketing authorization holder: Eureco-Pharma B.V.

Boelewerf 2

2987 VD Ridderkerk Netherlands

Registered under: RVG 127560

This medicine is registered in member states of the European Economic Area under the following names:

Denmark: Perxine

Finland: Perxine 50 mg/g emulsion cream Germany: Permethrin Infectopharm 50 mg/g

Cream Italy: InfectoScab

Netherlands: Permethrin InfectoPharm, 50 mg/g, cream Norway: Perxine

Portugal: InfectoScab

This leaflet was last approved in September 2024.