

Permethrin

5% w/w Cream

Permethrin Cream is not known to interact with any medicines.

Pregnancy, breast-feeding and fertility

For precautionary reasons, you should not use Permethrin Cream during pregnancy unless your doctor advise you to do so. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Driving and using machines

No effect on the ability to drive and use machines is to be expected.

Permethrin Cream contains butylhydroxytoluene (E321)

Permethrin Cream contains butylhydroxytoluene (E321) 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).

Permethrin Cream contains lanolin

Permethrin Cream contains lanolin as lanolin alcohols/liquid paraffin mixture which may cause local skin reactions (e.g. contact dermatitis). 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.

Permethrin Cream contains cetostearyl alcohol

Permethrin Cream contains cetostearyl alcohol as macrogol cetostearyl ether which may cause local skin reactions (e.g. contact dermatitis).

Permethrin Cream contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate

Permethrin Cream contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate. These excipients of the cream can may cause allergic reactions (possibly delayed).

The container of this medicinal product contains latex rubber. May cause severe allergic reactions.

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

3. How to use Permethrin Cream

Always use Permethrin Cream exactly as described in this leaflet or 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 Permethrin 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). The application should be repeated 7 – 14 days after the first treatment.

Children aged from 6 - 12 years: Apply up to 15 g of cream (corresponding to ½ tube of 30 g). The application should be repeated 7 – 14 days after the first treatment.

Children aged from 2 months - 5 years: Apply up to 7.5 g of cream (corresponding to ¼ tube of 30 g). The application should be repeated 7 – 14 days after the first treatment.

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.

Read all of this leaflet carefully before you start 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 Permethrin Cream is and what is it used for
2. What you need to know before you use Permethrin Cream
3. How to use Permethrin Cream
4. Possible side effects
5. How to store Permethrin Cream
6. Contents of the pack and other information

1. What Permethrin Cream is and what is it used for

Permethrin 5% w/w 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. You must talk to a doctor if the symptoms worsen or do not improve.

2. What you need to know before you use Permethrin Cream

Do not use Permethrin Cream

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

Warnings and precautions

Talk to your doctor or pharmacist before using Permethrin 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 Permethrin Cream after speaking to your doctor.

Carers who apply permethrin are advised to wear gloves.

Warning

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

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. Permethrin Cream may worsen symptoms of asthma or eczema.

Children up to 23 months of age

Do not use Permethrin 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.

Other medicines and Permethrin Cream

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Corticosteroids (steroids) should not be used to treat skin conditions like eczema when Permethrin 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.

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 Permethrin Cream?

Permethrin 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.

For treatment of scabies: Adults, adolescents and children over 2 years 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.

Children under 2 years of age, 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.

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.

How long should you use Permethrin Cream?

One application of Permethrin Cream is usually sufficient.

For scabies: 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 8-12 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.

For crab lice: The cream should be left on for 24 hours and then washed off 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.

If you use more Permethrin Cream than you should

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.

If you forget to apply Permethrin Cream

Do not apply a double quantity to make up for a forgotten application.

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 Permethrin 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 Permethrin 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 Permethrin 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 Permethrin 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 or pharmacist. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Permethrin Cream

This medicinal product does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use Permethrin 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. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater. 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 Permethrin Cream contains

The active substance is permethrin. Each g of cream contains 50mg permethrin.

The other ingredients are: butylhydroxytoluene (E321); carbomers; coconut oil, refined; glycerol (E422); glycerol monostearate 40-55; isopropyl myristate; lanolin alcohol/liquid paraffin mixture; macrogol (2) cetyl ether; macrogol cetostearyl ether; methyl parahydroxybenzoate (E218); propyl parahydroxybenzoate; sodium hydroxide (E524) and purified water.

What Permethrin Cream looks like and contents of the pack

Permethrin Cream is white to off-white, smooth, homogeneous cream.

Permethrin Cream is filled and packed in 30g aluminium collapsible tubes, fitted with white conical polypropylene cap.

Marketing Authorisation Holder

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