

Permethrin 5% w/w Cream

(permethrin)

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

- This medicine is available without prescription. However, you still need to use Permethrin 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 your symptoms worsen or do not improve after application of Permethrin Cream.
 - If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist straightaway.

In this leaflet:

1. What Permethrin Cream is and what it is used for
2. Before you use Permethrin Cream
3. How to use Permethrin Cream
4. Possible side effects
5. How to store Permethrin Cream
6. Further Information



1 What Permethrin Cream is and what it is used for

Permethrin Cream is used to treat infestations of scabies on the body. It contains the ingredient permethrin which belongs to a group of medicines called pyrethroids which kill mites such as scabies.

2 Before you use Permethrin Cream

Do not use Permethrin Cream if you are:

- Allergic to permethrin, other pyrethroids or pyrethrins, or to any of the other ingredients of (listed in section 6).

Warning 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:

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 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.

Permethrin Cream contains paraffins. 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 may worsen symptoms of asthma or eczema.

Take special care

If this product comes into contact with dressings, clothing and bedding the fabric can be easily ignited with a naked flame. You should keep away from fire when using this product.

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.

Taking 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 worse by interfering with the body’s natural defence to scabies.

Permethrin Cream is not known to interact with any medicines.

Important information about some of the ingredients of Permethrin Cream

Permethrin Cream contains cetostearyl alcohol which may cause local skin irritation (e. g. contact dermatitis)

Excipients

Permethrin creams contains 0.45g benzyl alcohol per tube. Benzyl alcohol may cause allergic reactions.

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

No effects are known on ability to drive and use machines.

3 How to use Permethrin Cream

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

Carefully apply a thin layer of cream to the skin (see “How and when should you use Permethrin Cream?”).

The table shows how much cream should normally be used:

| AGE | DOSAGE |
|--|--|
| Adults, the elderly & adolescents over 12 years of age | Apply up to 30 g of cream (corresponding to one tube of 30 g). A few adults may need to use an additional tube for full body coverage but should not use more than 2 tubes (60g in total) at each application. |
| Children aged from 6 to 12 years | Apply up to 15 g of cream (corresponding to half a tube of 30 g). |
| Children 1 to 5 years | Up to 7.5g of cream (corresponding to a quarter of a tube 30g). |
| Children 2 months to 1 year | Up to 3.75 g of cream (corresponding to an eighth of a tube of 30g). |

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.

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.

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 apply to broken 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.

Adults and adolescents over 12 years of age:

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.

Older children should be supervised by an adult when applying to ensure that a thorough treatment is administered.

Children over 2 years

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 their hands. If necessary, children should wear gloves.

Elderly (over 65 years old):

Apply as directed for adults but in addition, the face, ears and scalp should also be treated. Pay special attention to the areas between fingers and toes, under nails, wrists, armpits, breasts, external genitals, and buttocks. Care should be taken to avoid applying the cream to areas of skin around the eyes.

How long should you use Permethrin Cream?

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 eight hours, take a shower or wash the skin with soap and water. The application should be repeated 7 – 14 days after the first treatment.

If you are in doubt about the success of treatment, talk to your doctor or pharmacist.

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.

If you forget to apply Permethrin Cream

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

4 Possible side effects

Like all medicines, Permethrin Cream 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.

Continued on the next page >>

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

Very rarely, skin lesions due to skin picking disorder (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, pharmacist or nurse. 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

Keep out of the sight and reach of children.

Do not use after the expiry date shown 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 medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Further Information

What Permethrin Cream contains

The active substance is Permethrin (5% w/w).

The other ingredients are: cetylstearyl alcohol, white soft paraffin, macrogol cetostearyl ether, isopropylmyristate, benzyl alcohol and purified water.

Contents of the pack

Each tube contains 30 g of Permethrin Cream.

Marketing Authorisation Holder

Sandoz Limited, Park View, Riverside Way, Watchmoor Park, Camberley, Surrey, GU15 3YL, United Kingdom

Manufacturer:

Sandoz Limited, Park View, Riverside Way, Watchmoor Park, Camberley, Surrey, GU15 3YL, United Kingdom






or

Sofar S.P.A, Via Firenze, 40 – 20060, Trezzano Rosa (MI), Italy

This leaflet was last revised in 03/2025

00000000

Artwork Proof Box:

| | | | |
|------------------------|------------|---|--|
| Variation: | V039: RFI | Technical Colours: | |
| Proof no: | 014.1 |  Legend: | |
| Date prepared: | 29/08/2025 |  Cutting: | |
| Font size: | 6 pt |  TextArea: | |
| Fonts: | Helvetica |  Guides: | |
| Dimension: | 170x360 | | |
| Technical data: | | | |
| SKUs: | N/A | | |
| SZ codes: | N/A | | |
| Item codes: | 00000000 | Colours: | |
| Pharma codes: | 29 |  Black | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |



| | |
|--|--|
| | |
| | |
| | |