

Permethrin 5% w/w 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 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 one 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:

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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 (hypersensitive) to permethrin, to other pyrethroids or pyrethrins, or to any of the other ingredients of Permethrin Cream (see section 6).

Warning and precautions

Talk to your doctor or pharmacist before using Permethrin Cream:

- If you are known to be allergic to chrysanthemums or other compositae - you should only use Permethrin Cream after speaking to your doctor.

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.

Carers who apply permethrin are advised to wear gloves.

Taking other medicines

Corticosteroids (steroids) should not be used to treat skin conditions like eczema when Permethrin Cream is



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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.

Pregnancy and breast-feeding

As with all medicines, if you are pregnant or breast feeding, consult your doctor before using Permethrin Cream during pregnancy or while breast feeding.

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.

Excipients

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

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How to use Permethrin 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 apply to broken skin. Do not take a hot bath or shower immediately before treatment.

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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 Permethrin 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 Permethrin 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 neck, face, ears and scalp. Pay special attention to the areas between fingers and toes, under nails, wrists, armpits, breasts, external genitals and buttocks. Avoid the area around the eyes.

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

Keep your child from licking the cream from their hands. If necessary, children should wear gloves.

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

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, Permethrin Cream can cause side effects, although these are rare and usually mild.

- Commonly sensations on the skin (paraesthesias) such as tingling, pricking, skin burning sensation.
- Treatment of scabies may result in continued or increased irritation for a short while. This may show as redness or swelling 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 Permethrin Cream. This is normal and caused by an allergic reaction to the dead scabies mites. It is not a sign that treatment has failed.

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.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Permethrin Cream contains

The active ingredient 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 Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, UK.

Manufacturer:

Sandoz Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, UK or Sofar S.p.A., Via Firenze, 40 – 20060, Trezzano Rosa (MI), Italy.

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