

Package leaflet: Information for the patient

GB 675-2083-APIL



Hydrocortisone Cream 1%

(Hydrocortisone acetate)

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

- Please keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What Hydrocortisone Cream 1% is and what it is used for
2. What you need to know before you use Hydrocortisone Cream 1%
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1. What Hydrocortisone Cream 1% is and what it is used for

The name of your medicine is Hydrocortisone Cream 1%.

Hydrocortisone Cream 1% contains the active ingredient hydrocortisone which belongs to a group of medicines called corticosteroids or 'steroids'. Steroids like hydrocortisone are applied to the skin to reduce inflammation. Hydrocortisone Cream 1% is used to treat all types of eczema and dermatitis and insect bite reactions.

Corticosteroid creams, ointments and other topical preparations come in four different strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent corticosteroid has a much stronger effect than a mild corticosteroid. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Hydrocortisone cream 1% is classed as a mild potency corticosteroid.

Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

2. What you need to know before you use Hydrocortisone Cream 1%

Do not use Hydrocortisone Cream 1%:

- if you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6) (allergic reactions include mild

symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing).

- If you have an infection of the skin which has not been treated;
- If you have pale or reddened patches of skin – (usually as a result of an allergy; this is a condition known as urticaria);
- If you have a facial skin condition known as rosacea;
- If you have ulcers or an infection at the site of treatment;
- If you have psoriasis (a skin condition).

Warnings and precautions

Talk to your doctor or pharmacist before using Hydrocortisone Cream 1% if you:

- have TB (tuberculosis);
- have diabetes.

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.

Contact your doctor if you experience blurred vision or other visual disturbances.

If any of the above applies to you, or you are not sure please tell your doctor or pharmacist before you use this medicine.

If there is a worsening of your condition during use, consult your doctor - you may be experiencing an allergic reaction, have an infection, or your condition requires a different treatment.

If you experience a recurrence of your condition, shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your doctor unless, your doctor has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Other medicines and Hydrocortisone Cream 1%

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 using this medicine.

3. How to use Hydrocortisone Cream 1%

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Check that the tube seal is not broken before use. Use the point on the cap to break the seal.

For adults and children

Apply sparingly to the affected area of skin two or three times daily.

Important Information

- Use sparingly
- Avoid using the cream continuously for a long time, particularly in children and on the face.

If you use more Hydrocortisone Cream 1% than you should

If you accidentally use too much cream it is not likely to cause any harm.

If anyone accidentally swallows any cream, rinse out the mouth and seek medical advice. Take the product and packaging with you.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice;

- a skin rash,
- reddening of the skin or itching of the skin

stop using the cream and tell your doctor immediately. These may be signs of an allergic reaction.

Other side effects may include:

- spread of infection;
- permanent 'stretch-mark' like marks;
- thinning of the skin;
- changes in hair growth;
- acne;
- oily skin;
- slight loss of colour in the skin;
- blurred vision (uncommon - may affect up to 1 in 100 people).

If you use Hydrocortisone Cream 1% for a long time, very occasionally, this may lead to problems with your hormones. This mainly happens if it is used in areas such as the folds of the skin, the face and the nappy area, or in areas where a dressing is used to cover the area after using the cream.

Steroid withdrawal reaction:

If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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 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 Hydrocortisone Cream 1%

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

Do not store above 25°C.

Do not use any medicine after the expiry date on the carton and tube and keep them in their original pack.

Do not throw away any medicines via wastewater or household waste. 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 Hydrocortisone Cream 1% contains

The active ingredient is hydrocortisone acetate present at a concentration of 1%. The other inactive ingredients are: cetomacrogol emulsifying wax, liquid paraffin, white soft paraffin, chlorocresol and purified water.

What Hydrocortisone Cream 1% looks like and the contents of the pack

Hydrocortisone Cream 1% is a soft, white cream, with a faint characteristic odour.

It is available in a tube containing either 15 g, 30 g or 50 g of cream.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sovereign Medical,
Sovereign House, Miles Gray Road, Basildon,
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Manufacturer

Waymade Plc,
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