

Package leaflet: Information for the user
Hydrocortisone 1% w/w Ointment
1% Hydrocortisone

Read all of this leaflet because it contains important information for you.

This medicine is available without a prescription. However, you still need to use this product 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 talk to a doctor if you do not feel better or if you feel worse after 7 days.
- 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 Ointment is and what it is used for
2. What you need to know before you use Hydrocortisone Ointment
3. How to use Hydrocortisone Ointment
4. Possible side effects
5. How to store Hydrocortisone Ointment
6. Contents of the pack and other information

1. What Hydrocortisone Ointment is and what it is used for

Hydrocortisone Ointment is a smooth off-white ointment for application to the skin only. It contains hydrocortisone which belongs to a group of medicines called corticosteroids. Hydrocortisone Ointment is used to reduce inflammation in a variety of inflammatory skin conditions, such as:

- mild to moderate eczema
- dermatitis caused by irritants or allergens
- insect bite reactions

Hydrocortisone should not be confused with anabolic steroids, used by some body builders and taken as tablets or injections.

2. What you need to know before you use Hydrocortisone Ointment

Do not use Hydrocortisone Ointment:

- if you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6).
- if you have a bacterial infection (e.g. impetigo), viral infection (e.g. cold sores 'herpes simplex', chicken pox) or fungal infection (e.g. tinea, also called 'athlete's foot', ringworm or thrush) of the skin.
- on your face or near your eyes, on the anal or genital region, or on broken skin.

Take special care with Hydrocortisone Ointment

Hydrocortisone Ointment is **not** suitable for use in the following:

- allergic skin reactions including temporary red or raised areas on your skin (short lived 'wheal and flare' reactions)
- conditions involving the deeper skin layers, such as granulomas
- psoriasis (long term scaly skin condition); only use this product on medical advice and with careful supervision by your doctor.

Do not cover the area with a plaster or dressing of any kind after application of Hydrocortisone Ointment.

Take great care to apply the ointment sparingly to the skin of infants or children, especially in the nappy area which can be covered for long periods. Covering the treated area can increase absorption. Treatment for infants must not exceed 7 days.

Do not apply the product to your face for long periods of time.

If your condition worsens during use consult a pharmacist or 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/ointment without consulting a pharmacist or doctor. 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 Ointment

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor if you are or may be pregnant. Ask your doctor for advice before taking any medicine during pregnancy. There is a very small risk of abnormalities in the unborn child if this product is used during pregnancy. If you are breast-feeding, do not apply the product to your chest area.

Hydrocortisone Ointment contains wool fat

Hydrocortisone Ointment contains **wool fat** (lanolin) which may cause local skin reactions (e.g. contact dermatitis).

3. How to use Hydrocortisone Ointment

FOR EXTERNAL USE ONLY

Always use this medicine exactly as instructed in this leaflet. Check with your doctor or pharmacist if you are not sure.

Do not exceed the stated dose.

Not for use by children under 10 years of age without medical advice.

For application to the **surface of the skin** only:

1. Wash your hands thoroughly before use.
2. Apply the ointment sparingly to the affected area, once or twice a day for a **maximum of 7 days**. Massage the ointment gently into the affected area to help absorption into the skin.
3. Once applied, **do not cover** the area with a dressing or plaster.

If the condition has not improved after 7 days, or worsens, consult your doctor.

If you use more Hydrocortisone Ointment than you should

If you or a child accidentally swallow the ointment, contact your doctor or nearest hospital immediately. Take the packet with you to help identification.

If you forget to use Hydrocortisone Ointment

If you miss a treatment, apply the ointment as soon as you remember, and apply the remaining dose for that day at evenly spaced intervals.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Hydrocortisone Ointment can cause side effects, although not everybody gets them.

You may notice the following:

- rash, itchy skin, swelling of the lips, eyes, tongue, or difficulty in breathing may be signs of an **allergic reaction**. **Stop using Hydrocortisone Ointment immediately.**
- 'stretch marks' may appear, especially where skin is in folds such as the groin or armpits.
- Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on 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 directly via the national reporting systems below:

United Kingdom: Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Malta: ADR Reporting. Website: www.medicinesauthority.gov.uk/adrportal.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydrocortisone Ointment

Keep out of the sight and reach of children. Do not store above 25°C. Store in the original package and keep the tube in the outer carton. Do not use Hydrocortisone Ointment after the expiry date which is stated on the tube/carton. 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 Ointment contains:

- The **active substance** is hydrocortisone and the ointment contains 10 mg in every 1 g (1%).
- The **other ingredients** are wool fat (lanolin), liquid paraffin and white soft paraffin (*see end of Section 2 for further information*).

What Hydrocortisone Ointment looks like and contents of the pack

The product is a smooth, off-white ointment and is available in aluminium tubes containing 15 g.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

PL 04917/0020

MA 143/00102

Other formats: To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference number
Hydrocortisone 1% w/w Ointment	04917/0020

This is a service provided by the Royal National Institute of Blind People.

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