

PATIENT INFORMATION LEAFLET

HYDROCORTISONE OINTMENT 1% 1% Hydrocortisone

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Hydrocortisone Ointment is and what it is used for
2. Before you use Hydrocortisone Ointment
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4. Possible side effects
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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 including eczema and dermatitis of all types, such as:

- inherited skin inflammation, scaliness or itchiness (atopic eczema)
- light-sensitive skin (photodermatitis)
- dermatitis between folds of skin (intertrigo)
- dermatitis caused by irritants or allergens
- lumps in the skin with itching (prurigo nodularis)
- scaly or crusty skin, 'cradle cap' (seborrhoeic dermatitis)
- insect bite reactions.

2. BEFORE YOU USE HYDROCORTISONE OINTMENT

Do not use Hydrocortisone Ointment if you:

- are allergic to hydrocortisone or to any of the other ingredients of Hydrocortisone Ointment (*see Section 6 and end of Section 2*).
- have a bacterial infection (e.g. impetigo), viral infection (e.g. herpes simplex) or fungal infection (e.g. tinea, also called 'athlete's foot', ringworm or thrush) of the 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.

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.

Your doctor may advise the use of antimicrobial medicine at the same time as Hydrocortisone Ointment if the area has become infected.

Taking other medicines

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.

Important information about some of the ingredients

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

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3. HOW TO USE HYDROCORTISONE OINTMENT

FOR EXTERNAL USE ONLY

Always use Hydrocortisone Ointment exactly as your doctor has told you. Your doctor will tell you how much to apply and how often, but you must check with your doctor if you are not sure.

Do not exceed the stated dose.

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, one to four times a day. 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.

Increase the intervals between applications as the condition improves. Treatment may be reduced to two to three times a week, or restarted when your symptoms return.

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 doses 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 in skin folds such as the groin or armpits.

If any of the side effects become severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE HYDROCORTISONE OINTMENT

Keep out of the reach and sight 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.

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 Hydrocortisone Ointment contains:

- The **active substance** is hydrocortisone and the ointment contains 10 mg in every 1g (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 5g, 10g, 15g, 20g, 30g or 50g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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