

Package leaflet: Information for the user HYDROCORTISONE 1% W/W CREAM 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.
- · If you have any further questions, ask your pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve 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:

- What Hydrocortisone Cream is and what it is used for
- 2. Before you use Hydrocortisone Cream
- 3. How to use Hydrocortisone Cream
- 4. Possible side effects
- 5. How to store Hydrocortisone Cream
- 6. Contents of the pack and other information

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

Hydrocortisone Cream is a smooth white cream for application to the skin only. It contains hydrocortisone which belongs to a group of medicines called corticosteroids. Hydrocortisone Cream 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.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or 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 or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. Be aware the percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Hydrocortisone Cream is classed as a mild corticosteroid.

2. Before you use Hydrocortisone Cream

Do not use Hydrocortisone Cream:

- 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 Cream

Hydrocortisone Cream 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 Cream.

Take great care to apply the cream 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 Cream

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

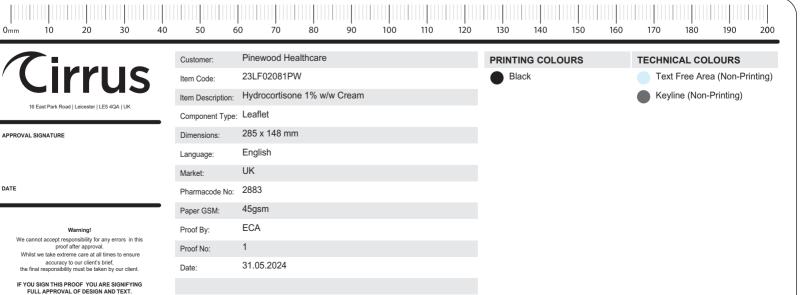
Tell your doctor if you are or may be pregnant. Ask your doctor for advice before taking any medicine during pregnancy. There is a very small risk of abnormalities in the unborn child if this product is used during pregnancy. If you are breast-feeding, do not apply the product to your chest area.

Hydrocortisone Cream contains chlorocresol and cetostearyl alcohol

- · chlorocresol may cause allergic reactions
- cetomacrogol emulsifying wax which contains cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

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3. How to use Hydrocortisone Cream

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 cream sparingly to the affected area, once or twice a day for a maximum of 7 days. Massage the cream 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 Cream than you should

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

If you forget to use Hydrocortisone Cream

If you miss a treatment, apply the cream 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 Cream 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 Cream immediately.
- 'stretch marks' may appear, especially in skin folds such as the groin or armpits.
- · 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 directly via the Yellow Card Scheme:

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

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 Cream 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. Contents of the pack and other information

What Hydrocortisone Cream contains:

- The active substance is hydrocortisone and the cream contains 10 mg in every 1 g (1%).
- The other ingredients are Cetomacrogol Emulsifying Wax, chlorocresol, liquid paraffin, Macrogol 300, white soft paraffin and purified water (see end of Section 2 for further information).

What Hydrocortisone Cream looks like and contents of the pack

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

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland. PL 04917/0019

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 cream	04917/0019

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

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