

# HYDROCORTISONE 0.5 %, 1 % AND 2.5 % m/m CREAM

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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

- 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 is and what it is used for**
2. **What you need to know 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 mild topical (applied to the skin) corticosteroid, or ‘steroid’ (not to be confused with ‘anabolic’ or ‘sex’ steroids).

Hydrocortisone Cream is used for inflamed skin conditions such as eczema, many types of dermatitis and insect bite reaction.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE HYDROCORTISONE CREAM

### Do NOT use Hydrocortisone Cream if you:

- are allergic (hypersensitive) to hydrocortisone or any of the other ingredients of this medicine
- have any other skin infection such as athlete’s foot (tinea pedis), chickenpox (varicella) or shingles (Herpes zoster), coldsores (Herpes simplex), impetigo, ringworm or thrush, infected lesions, ulcerative conditions, red appearance on face, peri-oral dermatitis or acne.

### Warnings and precautions

#### Talk to your doctor or pharmacist before you start to use this medicine if you:

- have psoriasis; the condition may become worse after stopping long-term treatment
- will be applying the cream to your face. This cream should not be used for long on the face as it may damage the facial skin
- will be using the cream for the treatment of dermatitis or nappy rash on children and infants. In this case the courses of treatment should not normally exceed 7 days
- are using this cream under occlusive dressing that can considerably increase the absorption of this cream.

Caution should be taken to keep away from the eyes.

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

If there is a worsening of your condition during use consult your prescriber – 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 your prescriber unless your prescriber has previously advised you to 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.

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.

### **Other medicines and Hydrocortisone Cream**

- Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

### **Pregnancy, breast-feeding and fertility**

- 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.

### **Driving and using machines**

- Hydrocortisone Cream is not expected to affect your ability to drive or operate machinery.

### **Important information about some of the ingredients of Hydrocortisone Cream**

- Hydrocortisone Cream contains **Chlorocresol** which may cause allergic reactions.

## **3. HOW TO USE HYDROCORTISONE CREAM**

Always use Hydrocortisone Cream exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Wash your hands before and after applying Hydrocortisone Cream, but if applying to the hands, do not wash after application.

- Use the spike in the top of the cap to make a hole through the seal of the tube
- Apply sufficient cream to thinly cover the affected area and gently rub into the skin until it disappears
- If the affected area becomes weepy or infected, stop using the cream and speak to your doctor. You may need to start antibiotic treatment, especially if the infection spreads
- You should not normally use Hydrocortisone Cream on the face for many weeks or months, unless specifically prescribed by your doctor.

The usual dose is:

#### **Adults (including the elderly)**

- Apply thinly two to three times a day, reducing as the skin heals.

#### **Children and Infants**

- Apply as for adults but avoid long term use. Treatment should be limited to seven days – especially in infants
- The lowest concentration suitable should be used; 2.5 % should not normally be used for children or infants
- Do not use under a nappy or an airtight dressing (such as a plaster) on an infant because this will enable too much active ingredient to pass through the skin.

### **If you use more Hydrocortisone Cream than you should**

If you squeeze out too much cream, wipe off the excess with a paper towel. Do not use the cream under airtight dressings (such as plasters) or nappies, as too much hydrocortisone may be absorbed and may result in adverse effects upon adrenal gland function.

### **If you forget to use Hydrocortisone Cream**

If you forget to apply the Hydrocortisone Cream, apply it as soon as possible and carry on as before. If it is 3 hours or less until the next application, then ignore the missed dose.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Hydrocortisone Cream can cause side effects, although not everybody gets them. Most patients using Hydrocortisone Cream will have no problems when used in the correct amount for the prescribed time.

If the following happens, stop using the cream and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives). This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Other effects which may occur:

- The skin may become thinner when used in the nappy areas of children where conditions are moist
- If Hydrocortisone Cream is used often over a large area of skin or for a long time, especially under dressings, adverse effects on adrenal gland function are more likely. These effects are also more likely in children and infants
- Prolonged use, especially on sensitive areas including skin folds, may result in thinning of the skin, widening of the blood vessels, stretch marks and may suppress the functioning of the adrenal gland
- 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.
- Blurred vision. This side effect has been reported, but the frequency for it to occur is not known.

If your condition becomes worse during treatment, you may have an allergy to one of the ingredients of the cream or an infection. Stop using the cream and tell your doctor as soon as possible.

### **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 at: [www.mhra.gov.uk/yellowcard](http://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 this medicine out of the sight and reach of children.**

Hydrocortisone Cream should be stored below 25°C and not frozen.

Do not use Hydrocortisone Cream after the expiry date which is stated on the carton or on the tube after EXP. The expiry date refers to the last day of that month.

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 to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Hydrocortisone Cream contains:**

- The active substance is hydrocortisone
- The other ingredients are white soft paraffin, cetomacrogol emulsifying wax, liquid paraffin, chlorocresol, and purified water.

### **What Hydrocortisone Cream looks like and contents of the pack:**

- Hydrocortisone 0.5 %, 1 %, and 2.5 % Cream is an aqueous cream
- Hydrocortisone 0.5 %, 1 %, and 2.5 % Cream is available in 15 g tubes. Hydrocortisone 1 % Cream is also available in 30 g and 50 g tubes.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation holder and company responsible for manufacture is TEVA UK Limited, Eastbourne BN22 9AG.

Or

Marketing Authorisation holder: TEVA UK Limited, Eastbourne, BN22 9AG England  
and company responsible for manufacture: Teva Pharmaceutical Works Private Limited, Pallagi Street 13, Debrecen, H 4042, Hungary

**This leaflet was last revised: August 2021**

PL 00289/0753-0755