

HYDROCORTISONE 1 % 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.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- This medicine is available without prescription. However, you still need to use Hydrocortisone Cream 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.
- 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.
- You must talk to a doctor if you do not feel better, or if your symptoms worsen or do not improve after 7 days.

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 the relief of mild inflammatory skin disorders including:

- mild to moderate eczema
- irritant contact dermatitis or allergic contact dermatitis
- insect bite reactions.

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
- are going to apply the cream to your face, eyes or ano-genital region, or to broken or infected skin (including cold sores, acne, athlete's foot or chickenpox).
- are going to apply the cream under occlusive dressing.

Warnings and precautions

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

- are going to use the cream on a child under 10 years old.

Stop using this cream and consult a doctor immediately if you experience any allergic type reactions after using this cream or if your condition does not improve even after using this cream.

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

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 described in this leaflet or as your doctor or pharmacist has told you. Otherwise follow the instructions below. Check with your doctor or pharmacist if you are not sure.

- Use the spike in the top of the cap to make a hole through the seal of the tube.
- Wash your hands before and after applying Hydrocortisone Cream but if applying to the hands do not wash after application.
- If symptoms persist after 7 days, consult your doctor.
- **Adults (including the elderly) and children over 10 years old**
Apply sufficient cream once or twice a day to thinly cover the affected area and gently rub into the skin until it disappears. Use the cream for a maximum period of one week.
- **Children under 10 years**
Do not use in children under 10 years without speaking to your doctor first.

If you use more Hydrocortisone Cream than you should

If you have squeezed out too much cream, wipe off the excess with a paper towel.

If you forget to use Hydrocortisone Cream

If you forget to apply Hydrocortisone Cream, apply it as soon as possible and carry on as before. If it is 4 hours or less to 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.
- 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 Hydrocortisone Cream and tell your doctor as soon as possible.

Use of this cream may cause stretch marks on the skin.

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, 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.

Store Hydrocortisone Cream below 25°C and do not freeze.

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 1% w/w 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 Cream is an aqueous cream.
- Hydrocortisone Cream is available in 10 g and 15 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: April 2019
PL 00289/0759