

HYDROCORTISONE 1%w/w CREAM

Hydrocortisone 1%w/w PA 206/30/1

PATIENT INFORMATION LEAFLET

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

This medicine is available without a prescription. Nevertheless, you will still need to use Hydrocortisone 1%w/w 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 of the side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.
- You must see a doctor if your symptoms do not improve after using Hydrocortisone 1%w/w Cream.

In this leaflet:

1. What Hydrocortisone 1%w/w Cream is and what it is used for
2. Before you use Hydrocortisone 1%w/w Cream
3. How to use Hydrocortisone 1%w/w Cream
4. Possible side effects
5. How to store Hydrocortisone 1%w/w Cream
6. Further information

1. WHAT HYDROCORTISONE 1% W/W CREAM IS AND WHAT IT IS USED FOR

The name of your treatment is Hydrocortisone 1%w/w Cream. It is a smooth white aqueous cream. Hydrocortisone 1%w/w Cream contains hydrocortisone 1%w/w as the active ingredient. Hydrocortisone 1%w/w Cream is one of a group of medicines called corticosteroids. It works by lowering the production of substances that cause inflammation. It is used to relieve the itching, redness, swelling, dryness, inflammation and discomfort of various skin conditions (contact dermatitis, irritant dermatitis, insect bite reactions and mild to moderate eczema).

2. BEFORE YOU USE HYDROCORTISONE 1% W/W CREAM

Do not use Hydrocortisone 1%w/w Cream

- On the eyes or face, the ano-genital region or on broken or infected skin including cold sores, acne and athletes foot.
- In the presence of untreated infections of bacterial, viral, tuberculosis or fungal origin.
- In the presence of acne, rosacea or on dermatitis affecting the area around the mouth or nose.
- If you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in Section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you have any kind of infection this includes infections caused by viruses, bacteria or fungus or if you are being treated for tuberculosis.
- If you have perioral dermatitis, acne, acne rosacea or psoriasis. Use of this product if you have psoriasis may cause your psoriasis to get worse or it could make your psoriasis return once you stop using the cream.

Warnings and Precautions

- Hydrocortisone 1%w/w Cream is not recommended for use in children under 12 years without medical supervision.
- Do not bandage the treated area unless directed to do so by your doctor.
- Continuous application without interruption will result in permanent damage of the skin, particularly on the face.
- Talk to your doctor or pharmacist before using this product if you have an adrenal gland tumour (pheochromocytoma).
- Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) and chlorocresol may cause allergic reactions.

Pregnancy and breast-feeding

Hydrocortisone 1%w/w Cream should not be used in pregnancy unless considered essential by your doctor, and then over as small an area and for as short a time as possible. Ask your doctor or pharmacist for advice before taking any medicine.

Other medicines and Hydrocortisone 1%w/w Cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

Hydrocortisone 1%w/w Cream contains white soft paraffin, cetomacrogol emulsifying wax (cetostearyl alcohol and macrogol cetostearyl ether), liquid paraffin, chlorocresol and purified water.

3. HOW TO USE HYDROCORTISONE 1% W/W CREAM

Hydrocortisone 1%w/w Cream should be applied sparingly in a thin film and rubbed in gently with your fingertips. Hydrocortisone 1% w/w Cream should be applied once or twice daily for a maximum period of one week (7 days), or as directed by your doctor. When skin condition improves, frequency of application can be gradually reduced. Do not cover the area with a plaster or any dressings (including nappies).

How to apply this medicine

If your doctor has asked you to apply some ointment to the affected area, follow the instructions below on how to apply this medicine:

- Wash your hands
- Squeeze a small amount of the ointment onto your fingertip
- Gently rub a small layer of ointment over the inflamed, itchy area
- Wash your hands

If you use more Hydrocortisone 1%w/w Cream than you should

Let your doctor know if you have used this ointment for more than 7 days by mistake. If you use more than you should, the side effects as described in section 4 "Possible Side Effects" can occur. Talk to your doctor or pharmacist.

If you forget to use Hydrocortisone 1%w/w Cream

Apply Hydrocortisone 1%w/w Cream as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Side effects with Hydrocortisone 1%w/w Cream are very rare. Local irritation, itching and burning may occur. Over use of hydrocortisone, or use under dressings or nappies, could potentially cause suppression of your adrenal glands which make hormones such as cortisol (symptoms may include weakness, fatigue, weight loss, lack of appetite, pain in the stomach, feeling sick or being sick, lack of concentration, a feeling of hunger, nervousness and fits). Over use can also affect your skin and may cause permanent thinning on your skin and more visible blood vessels and veins, particularly on the face or cause striae (stretch marks).

Allergic (hypersensitive) reaction to hydrocortisone

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2

Tel: +353 1 6764971; Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

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

5. HOW TO STORE HYDROCORTISONE 1%W/W CREAM

Keep out of the reach and sight of children. Store below 25°C, do not freeze. Do not use this medicine after the expiry date which is stated on the tube and outer carton 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. FURTHER INFORMATION

What Hydrocortisone 1%w/w Cream contains

The active substance is hydrocortisone. The other ingredients are white soft paraffin, cetomacrogol emulsifying wax (containing cetostearyl alcohol and macrogol cetostearyl ether), liquid paraffin, chlorocresol (as a preservative) and purified water.

What Hydrocortisone 1%w/w Cream looks like and contents of the pack

Hydrocortisone 1%w/w Cream is a smooth white aqueous cream for topical application to the skin. The tube contains 15g of cream.

PA Holder and Manufacturer

The PA holder and manufacturer is Ovelle Limited, Coe's Rd, Dundalk, Ireland.

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