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| Title: Fludroxycortide 0.0125% Cream | Colours (Printed)  Black Process | Colours (Non printed)  TRIM REFERENCE |
| Ref: FC/TY/PIL | | |
| Date: 08/11/15 | | |
| Size (mm): 148(W) x 300(H) | | |
| Modified: 03/02/24 | | |



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PACKAGE LEAFLET: INFORMATION FOR THE USER

Fludroxycortide 0.0125% w/w Cream

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 Fludroxycortide 0.0125% w/w Cream is and what it is used for
2. What you need to know before you use Fludroxycortide 0.0125% w/w Cream
3. How to use Fludroxycortide 0.0125% w/w Cream
4. Possible side effects
5. How to store Fludroxycortide 0.0125% w/w Cream
6. Contents of the pack and other information

1. WHAT FLUDROXYCORTIDE 0.0125% W/W CREAM IS AND WHAT IT IS USED FOR

Fludroxycortide 0.0125% w/w Cream is a white cream for application to the skin. Fludroxycortide 0.0125% w/w Cream belongs to a group of medicines called topical corticosteroids and is used to treat skin conditions such as eczema and dermatitis of all types, especially when the skin is moist or weeping. Fludroxycortide 0.0125% w/w Cream can be used in adults and children.

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. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Fludroxycortide is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FLUDROXYCORTIDE 0.0125% W/W CREAM

Do not use Fludroxycortide 0.0125% w/w Cream

- for skin tuberculosis.
- for rosacea of the face.
- for acne.
- for dermatitis around the mouth.
- for itchiness of the genitals or anus.
- for skin conditions in babies including eczema or napkin rash.
- for bacterial skin infections such as impetigo.
- for viral skin infections such as cold sores.
- for fungal skin infections such as athlete's foot.

Do not use Fludroxycortide 0.0125% w/w Cream if you are allergic to fludroxycortide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- **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.**
- Talk to your doctor or pharmacist before using Fludroxycortide 0.0125% w/w Cream.
- The cream should not be used on or near your eyes or inside your mouth.
- Do not use Fludroxycortide 0.0125% w/w Cream for long periods of time and do not cover it tightly under dressings or clothes.
- Do not use Fludroxycortide 0.0125% w/w Cream on large areas of damaged skin or in skin folds such as the armpits or groin area.
- Do not use Fludroxycortide 0.0125% w/w Cream on your face for more than five days and do not cover it up tightly.
- If you have a skin infection or think you have a skin infection, tell your doctor.

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 do 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.

Children



- Do not use Fludroxycortide 0.0125% w/w Cream on children's skin for more than five days and do not cover it up tightly.

Other medicines and Fludroxycortide 0.0125% w/w Cream

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

Do not use Fludroxycortide 0.0125% w/w Cream 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 taking this medicine.

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Important information about some of the ingredients of Fludroxycortide 0.0125% w/w Cream
Fludroxycortide 0.0125% w/w Cream contains cetyl alcohol and propylene glycol

Fludroxycortide 0.0125% w/w Cream contains cetyl alcohol which may cause local skin reactions such as contact dermatitis and propylene glycol which may cause skin irritation.

3. HOW TO USE FLUDROXYCORTIDE 0.0125% W/W CREAM

Always use this medicine exactly as your doctor has told you. Check the label for how to use your medicine and how often to use it. Only put the cream on the parts of your skin your doctor wants to treat. Check with your doctor or pharmacist if you are not sure.

Usual dose

Only use Fludroxycortide 0.0125% w/w Cream on your skin. Do not put it in your mouth or eyes. Apply the cream gently to the affected area of skin two or three times each day. If you are elderly your skin may be thin so you will need to apply the cream sparingly. If your doctor has told you to cover the skin tightly where you are using Fludroxycortide 0.0125% w/w Cream, you should only have to cover a small area.

If you forget to use Fludroxycortide 0.0125% w/w Cream

If you forget to use Fludroxycortide 0.0125% w/w Cream do not worry, just put on the next application when it is due. If accidentally swallowed, contact your nearest hospital casualty department or tell your doctor immediately. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some patients may have one or more of the following side effects in the area where they apply Fludroxycortide 0.0125% w/w Cream:

- Burning, itching, irritated or dry skin.
- Excess hair growth.
- Pale skin.
- Allergic contact dermatitis.
- Skin softening.
- Red spots or lines on the skin.
- Infected wounds may take longer to heal.
- Inflammation at the bottom of skin hairs.
- Acne pimples.
- Dermatitis around the mouth.
- Limp, flabby or thin skin where the cream was.
- Skin infections may get worse.
- Blood vessels in the skin become visible.

The amount of sugar in your blood and urine may change or some of your hormones may be affected causing weight gain, menstrual irregularities and hair growth. These effects are very rare. Some steroids are known to affect certain hormones. If your doctor thinks you need to be treated for longer periods of time, they may arrange for you to have hormone tests. If the cream is affecting your hormones, your doctor may tell you to stop using it. Then your hormones should return to normal. Children treated with topical steroids have rarely had high fluid pressure in their skulls. This has caused headaches and swelling.

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 at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card Scheme 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 FLUDROXYCORTIDE 0.0125% W/W CREAM

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Do not use this medicine after the expiry date which is stated on the tube crimp and on the 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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Fludroxycortide 0.0125% w/w Cream contains

- The active substance is fludroxycortide, 0.0125%w/w.
- The other ingredients are stearic acid, cetyl alcohol, polyoxyl 40 stearate, liquid paraffin, propylene glycol, sodium citrate, citric acid anhydrous and water.

What Fludroxycortide 0.0125% w/w Cream looks like and contents of the pack

Fludroxycortide 0.0125% w/w Cream is white and comes in a 60g aluminium tube.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Typharm Ltd, Unit 1, 39 Mahoney Green, Rackheath, Norwich, NR13 6JY.

Manufacturers

PURNA PHARMACEUTICALS NV/SA, Rijksweg 17, 2870 Puurs, Belgium.

This leaflet was last revised in January 2024.