



Title:	Fludroxycortide 0.0125% w/w Ointment	Colours (Printed)	Colours (Non printed)
Ref:	FO/TY/PIL		
Date:	08/11/15		
Size (mm):	148(W) x 300(H)		
Modified:	27/03/19		



**TYPHARM**  
LIMITED



**TYPHARM**  
LIMITED

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

## Fludroxycortide 0.0125% w/w Ointment

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

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

Fludroxycortide 0.0125% w/w Ointment is a white ointment for application to the skin. Fludroxycortide 0.0125% w/w Ointment belongs to a group of medicines called topical steroids and is used to treat skin conditions such as eczema and dermatitis of all types, especially when the skin is dry and scaly. Fludroxycortide 0.0125% w/w Ointment can be used in adults and children.

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

**Do not use Fludroxycortide 0.0125% w/w Ointment**

- 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 Ointment 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 Ointment.
- The ointment should not be used on or near your eyes or inside your mouth.
- Do not use Fludroxycortide 0.0125% w/w Ointment for long periods of time and do not cover it tightly under dressings or clothes.
- Do not use Fludroxycortide 0.0125% w/w Ointment 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 Ointment 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.

**Children**

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

**Other medicines and Fludroxycortide 0.0125% w/w Ointment**



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 Ointment 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.

**Important information about some of the ingredients of Fludroxycortide 0.0125% w/w Ointment**  
**Fludroxycortide 0.0125% w/w Ointment contains cetyl alcohol**

Fludroxycortide 0.0125% w/w Ointment contains cetyl alcohol which may cause local skin reactions such as contact dermatitis.

Title:	Fludrocortide 0.0125% w/w Ointment	Colours (Printed)	Colours (Non printed)
Ref:	FO/TY/PIL		
Date:	08/11/15		
Size (mm):	148(W) x 300(H)		
Modified:	276/03/19		



**TYPHARM**  
LIMITED

### 3. HOW TO USE FLUDROXYCORTIDE 0.0125% W/W OINTMENT

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 ointment 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 Fludrocortide 0.0125% w/w Ointment on your skin. Do not put it in your mouth or eyes. Apply the ointment 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 ointment sparingly. If your doctor has told you to cover the skin tightly where you are using Fludrocortide 0.0125% w/w Ointment, you should only have to cover a small area.

#### If you forget to use Fludrocortide 0.0125% w/w Ointment

If you forget to use Fludrocortide 0.0125% w/w Ointment 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 Fludrocortide 0.0125% w/w Ointment:

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

#### 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 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 OINTMENT

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 Fludrocortide 0.0125% w/w Ointment contains

- The active substance is fludrocortide, 0.0125%w/w.
- The other ingredients are white soft paraffin, white beeswax, cetyl alcohol and sorbitan sesquioleate.

#### What Fludrocortide 0.0125% w/w Ointment looks like and contents of the pack

Fludrocortide 0.0125% w/w Ointment is white and comes in a 60g aluminium tube.

#### Marketing Authorisation Holder and Manufacturer

##### Marketing Authorisation Holder

Typharm Ltd, 14D Wendover Road, Rackheath Industrial Estate, Norwich, NR13 6LH.

##### Manufacturers

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

This leaflet was last revised in March 2019.