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TYPHARM LIMITED

Package leaflet: Information for the user

Fludroxycortide 4 micrograms per square centimetre Tape

TYPHARM LIMITED

Fludroxycortide

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

1. WHAT FLUDROXYCORTIDE TAPE IS AND WHAT IT IS USED FOR

Fludroxycortide Tape is a thin plastic surgical tape. Each square centimetre contains 4 micrograms of the corticosteroid fludroxycortide. The tape is used on difficult to treat skin conditions, especially when the skin is dry and scaly.

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 TAPE

Do not use Fludroxycortide Tape

- for chicken pox
- for skin reactions to smallpox vaccination
- for tuberculosis of the skin
- 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 Tape if you are allergic to fludroxycortide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Fludroxycortide Tape.

- If you have ever had an allergic reaction to Fludroxycortide Tape (an allergic reaction may include a rash, itching, swelling or breathing difficulties) tell your doctor.
- If you have a skin infection or think you have a skin infection tell your doctor.
- If you are using the tape on your face, you should only use the tape for five days.
- Follow your doctor's instructions.

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 tape 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.

Children

Do not use Fludroxycortide Tape on children's skin for more than five days and do not cover it up tightly. This is because children may absorb more steroid medicine into their bodies than adults. If this happened for a long time it might stop them from growing or developing properly.

Other medicines and Fludroxycortide Tape

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 Tape 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.

3. HOW TO USE FLUDROXYCORTIDE TAPE



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

Usual doses

Check the label for how to use your medicine and how often to use it.
Only put the tape on the parts of your skin your doctor wants to treat.
Only use Fludroxycortide Tape on your skin. Do not put it in your mouth or over your eyes.



Fludroxycortide Tape is easy to use.
Please follow these instructions.

Cleaning the skin

Before you apply Fludroxycortide Tape, make sure the affected skin is clean and dry. If you need to shave the skin around the affected area, your doctor or nurse will tell you how to do it.



Fludroxycortide Tape is waterproof so, once it is in place, you can wash, bathe, shower or even swim. Its matt surface means that you can apply make-up over it.

Cutting the tape

You cannot tear Fludroxycortide Tape. Always cut it with clean scissors. Make sure that the piece you cut is big enough just to cover the affected area and about 0.5cm of unaffected skin all around.

Your doctor will tell you which area to treat. Round off the corners of the patch to stop it curling or catching on your clothes.

• Applying Fludroxycortide Tape

Once you have removed the paper backing, throw it away and apply the adhesive side of the clear tape to your skin. Take care the tape does not stick to itself as you take off the paper.

The tape will stick better if you stroke the back of it gently from the middle outwards.

If you need to cover an area of skin which is longer than 7 cm, do not take all the paper backing off when you cut the tape. Peel back a bit at a time as you stick the tape onto your skin.

• Fludroxycortide Tape is flexible

If the affected area is likely to be moving constantly, for example, because it is on your hands, fingers, feet, knees or elbows, apply the tape while the skin is flexed. Segments can be cut from the tape to allow you to mould the tape into shape over the affected area. If you are applying it to the outer surface of a knee or elbow, stick it on while the joint is bent. Then you should be able to bend the joint without disturbing the dressing.

• 'Awkward' areas

You may need someone to help you put Fludroxycortide Tape on areas which are difficult to reach.

Your doctor will tell you how long to use the tape for, this is usually 12 hours per day but can be longer.

Do not use Fludroxycortide Tape for long periods of time without speaking to your doctor.

Do not cover the tape with other dressings or tightly fitting clothes. 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 tape is affecting your hormones, your doctor may tell you to stop using it. Then your hormones should return to normal.

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.

A few patients may have one or more of the following side effects in the area where they apply Fludroxycortide Tape.

- Burning, itching, irritated or dry skin.
- Excessive hair growth.
- Acne pimples.
- Pale skin.
- Limp, flabby or thin skin where the tape was.
- Inflammation at the bottom of skin hairs.
- Red spots or lines on the skin.
- Dermatitis around the mouth or contact dermatitis.
- The amount of sugar in your blood and urine may change or your hormones may be affected, causing weight gain, menstrual irregularities and hair growth. These effects are rare.
- Skin infections may get worse if they are not treated with an antibiotic or other medicine.
- Wounds may take longer to heal.
- 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 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 TAPE

Keep this medicine out of the sight and reach of children.
Keep the plastic container tightly closed to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton after EXP.
The expiry date refers to the last day of that month.
Store in a dry place, below 25°C.

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 Tape contains

- The active substance is fludroxycortide (4 micrograms/cm^2).
- The other ingredients are acrylate copolymer adheisve, low-density polyethylene backing and silicone coated paper release liner.

What Fludroxycortide Tape looks like and contents of the pack

Fludroxycortide Tape is a translucent, polythene adhesive film, 7.5cm wide, protected by a removable paper liner.

It is available as a 20cm, 50cm or 200cm roll.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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