PACKAGE LEAFLET: INFORMATION FOR THE USER
Fluticasone propionate 0.05% cream

The name of your medicine is fluticasone propionate 0.05% cream which will be referred to as fluticasone throughout the rest of the leaflet.

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

1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR

Fluticasone propionate 0.05% cream is one of a group of medicines known as corticosteroids, which have a high anti-inflammatory effect when used topically.
Fluticasone is a corticosteroid that is applied to the skin to treat a wide variety of inflammatory skin diseases. It is used for the relief of inflamed skin, redness and itching in several skin problems not caused by germs and responsive to corticosteroids.
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. Fluticasone propionate 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 THIS MEDICINE

Do not use this medicine:
- If you are allergic to fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from rosacea (flushing and inflammation of the facial skin), acne vulgaris or perioral dermatitis (inflammatory rash around the mouth).
- If you have infections of the skin with viruses such as herpes simplex or chickenpox.
- If you suffer from perianal or genital pruritus (itching around the back passage and genitals).
- If you suffer from ulcers in the skin, atrophy (thinning of skin) or fragile skin vessels.
- If you suffer from ichthyosis (skin disorders characterised by dryness and fish skin-like scaling on the skin).
- If you suffer from juvenile dermatosis (any skin diseases characterised by inflammation) or dermatosis in infants under 1 year of age, including dermatitis (inflammation of the skin) and napkin eruptions.
- If you suffer from ulcerated injuries.
- If you suffer from infected skin lesions caused by infection with fungi or bacteria.

Warnings and precautions
Talk to your doctor or pharmacist before using this medicine:
- If you are pregnant, think you may be pregnant or if you are breast-feeding (see section Pregnancy, breast-feeding and fertility).
- If you use this medicine on large areas of the body for prolonged periods of time, especially when treating children, since it may increase the absorption of the product and the risk of toxicity.
- If you use this medicine on your face, since it may cause atrophic changes like thinning skin. It is important that you do not let the cream get in your eyes.
- If you use this medicine on covered parts of the body. Do not use this product under occlusive dressing; the affected zone has to be in contact with the air and not covered by dressing, tight clothes or similar. In infants, a nappy can act as an occlusive dressing. You should wash your skin before changing the dressing.
- If your doctor has prescribed this medicine for psoriasis. You should visit your doctor regularly to review your progress at periodic intervals.
- If you are using other products (including cosmetics) on the affected skin areas, as they can have a negative effect on this medicine's activity. Check with your doctor if you are not sure.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- 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 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.

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.

Children
Do not use the product in children under 1 year.
Tell your doctor if the symptoms do not improve within one or two weeks of starting treatment. Once the skin condition has improved (usually within one to two weeks), you should apply the cream less frequently. Using the cream daily for more than 4 weeks is not recommended.
This medicine should only be used in children to relieve inflamed skin, redness and itching caused by atopic dermatitis under supervision of a medical specialist. You should consult a dermatologist before using this medicine in other types of dermatoses in children.

Other medicines and fluticasone
Tell your doctor 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 for advice before taking this medicine.

Pregnancy
This medicine should only be used during pregnancy if the expected benefit to the mother outweighs the possible risk to the unborn child.

Breast-feeding
It is not known whether fluticasone is secreted in breast milk. This medicine should only be used during lactation if the expected benefit to the mother outweighs the possible risk to the child.

Driving and using machines
Fluticasone is not known to negatively affect the ability to drive or operate machinery.

This medicine contains cetostearyl alcohol, imidurea and propylene glycol.
As this medicine contains cetostearyl alcohol it may cause local skin reactions (e.g. contact dermatitis).

This medicine contains the preservative imidurea.
Imidurea breaks down to release a very small amount of chemical called formaldehyde. Formaldehyde may cause local skin reactions (e.g. contact dermatitis).

This medicine contains 100mg propylene glycol in 1 gram of cream.

3. HOW TO USE THIS MEDICINE

The doctor will prescribe an appropriate dosage for you.
Always use this medicine exactly as your doctor has told you.
Check with your doctor or pharmacist if you are not sure.
For adults and children aged 1 year and over, apply a thin film of this medicine to the affected skin areas once to twice daily unless otherwise instructed by your doctor. Ask your doctor about the duration of the treatment.
In some diseases (psoriasis, atopic dermatitis) it is not advisable to stop the treatment suddenly; you have to progressively reduce the number of applications. Follow the instructions your doctor gives to you.
Your doctor will tell you what the appropriate dose is for you if the symptoms appear again after a recovery. The usual dose is one application daily, 2 days per week.
It is not advisable to stop the treatment in some skin diseases such as psoriasis or atopic dermatitis. You should check the best way to finish treatment with your doctor.

Instructions for use:

1 Wash your hands.
2 Apply a thin film of the cream and rub gently until it has all disappeared.
3 Wash your hands, unless the cream is used to treat your hands.

If your skin problems do not improve within one to two weeks of starting treatment, tell your doctor.

If you use more of this medicine than you should
If you used more of this medicine than you should, especially in children, wash the affected areas of skin carefully to remove all the cream and contact your doctor or pharmacist. In case of accidental ingestion, contact your doctor or pharmacist.

If you forget to use this medicine
Do not use a double dose to make up for a forgotten one.
If you forget to apply your cream, apply the correct dose when you remember or, if it is close to your next application, then wait until this time.

If you stop using this medicine
Do not stop using this medicine, even if you feel better, unless advised by your doctor.
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.

Common side effects (may affect up to 1 in 10 patients):
- Itching (pruritus).

Uncommon side effects (may affect up to 1 in 100 patients):
- Local burning sensation.

Very rare side effects (may affect up to 1 in 10,000 patients):
- Secondary infections (an infection that occurs during or following treatment of another already existing infection), especially when occlusive dressings are used or when skin folds are involved.
- Hypersensitivity. You should discontinue the use of this medicine if signs of hypersensitivity appear.
- Hypercortisolism (increase of corticosteroid levels) due to the prolonged use of large amounts of corticosteroids, or treatment of extensive areas. This is more likely to occur in infants and children and if occlusive dressings are used.
- Dilatation of superficial blood vessels, due to prolonged and intensive treatment with potent corticosteroid preparations.
- Allergic contact dermatitis (allergic skin reactions).
- Worsening of signs and symptoms of dermatosis (skin reaction that involves skin inflammation).
- Pustular psoriasis caused by the treatment or its withdrawal.
- Atrophic local changes of the skin such as thinning, striae, hypertrichosis (excessive hair growth in a defined area) and hypopigmentation (skin discolouration) caused by prolonged and intensive treatment with potent corticosteroid preparations.

Not known (frequency cannot be estimated from the available data):
- Vascular purpura (a group of skin disorders characterised by purplish or brownish red discoloration).
- Skin fragility.
- Peri-oral dermatitis (inflammation of the skin around the mouth).
- Rosacea (flushing and inflammation of the facial skin).
- Scab.
- Leg ulcer.
- Acne.
- Impaired healing.
- Blurred vision.
- 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 (website: 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 THIS MEDICINE

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and the tube after 'exp'. The expiry date refers to the last day of that month.
Do not store above 30ºC.
Use within 6 months after first opening.
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.
Do not use this medicine if you notice any visible signs of deterioration.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What this medicine contains
- The active substance is fluticasone propionate. Each 100g of cream contains 0.05g of fluticasone propionate.
- The other ingredients are macrogol cetostearyl ether, cetostearyl alcohol, isopropyl myristate, paraffinum liquidum, purified water, propylene glycol (E-1520), citric acid monohydrate, disodium phosphate anhydrous, imidazolidinyl urea.

What this medicine looks like and contents of the pack
This medicine is a white, viscous cream contained in a 30g aluminium tube with a screw cap.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Aspire Pharma Ltd,
Unit 4, Rotherbrook Court
Bedford Road, Petersfield,
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