

Fluticasone Propionate

FLUTIPRO[®]

Composition:

Fluticasone Propionate	0.05% w/w
Imidurea (as Preservative)	0.2% w/w

Fluticasone Propionate Cream, 0.05% is a medium potency topical corticosteroid which works by reducing skin inflammation (redness, swelling, itching, and irritation).

Indications:

Flutipro can be used to treat:

Inflammation and itching caused by certain skin conditions. It may also be used for other conditions as determined by your doctor.

Flutipro is a medium potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. It may be used with caution in pediatric patients 3 months of age or older. The safety and efficiency of drug use for longer than 4 weeks in this population have not been established. The safety and efficacy of Fluticasone Propionate Cream, 0.05% in pediatric patients below 3 months of age have not been established.

Directions for use:

Flutipro cream is indicated for external use only. Do not apply to the face or in the eyes. Do not take by mouth. Follow the directions on the prescription label. Apply a thin film of cream or ointment to the affected area. Do not cover with a bandage or dressing unless your prescriber or health care professional tells you to. Wash your hands before and after use. Do not use your medicine more often than directed.

Contact your pediatrician or health care professional regarding the use of this medicine in children. Special care may be needed.

Elderly patients are more likely to have damaged skin through aging, and this may increase side effects. Corticosteroid skin preparations should only be used for brief periods and infrequently in older patients.

Before using Fluticasone Cream:

Some medical conditions may interact with Fluticasone Cream. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

- if you are pregnant, plan to become pregnant, or are breast-feeding
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- if you have allergies to medicines or other substances.
- if you have an acne-like rash, rosacea, inflammation around the mouth, skin thinning, a skin infection, measles, tuberculosis (TB), chickenpox, shingles, or a positive TB skin test
- if you are taking an oral corticosteroid (eg, prednisone) or similar medicines.

Side effects:

All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome:

- Dryness; mild stinging, burning, or itching.

Seek medical attention right away if any of these SEVERE side effects occur:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); acne-like rash; burning, cracking, irritation, or peeling not present before you began using Fluticasone Cream; excessive hair growth; inflamed hair follicles; inflammation around the mouth; thinning, softening, or discoloration of the skin.

Warning!

- Do not use Fluticasone propionate for any disorder other than the one for which it was prescribed.
- Do not use Flutipro cream on the face, underarms, or groin areas unless your doctor tells you to do so. Do not apply Flutipro if you have an infection in the affected skin area. Tell your doctor if you have had any other problems in that area.
- The treated skin area should not be bandaged, covered, or wrapped unless you have been directed to do so by your doctor.
- Do not apply Flutipro cream to the diaper area because covering a treated area with waterproof diapers or plastic pants can increase unwanted absorption of Flutipro.
- Do not use Flutipro to treat rosacea or skin inflammation near the mouth. Also avoid using Flutipro on thin, weakened skin that has lost its elasticity.
- If an irritation or allergic reaction develops while using Flutipro, notify your doctor.
- The drug can interfere with the thyroid, pituitary, and adrenal glands, causing a problem called Cushing's syndrome (weight gain, reddening of the face and neck, growth of excess facial hair, high blood pressure, and mental disturbances), hyperglycemia (excess glucose in the blood), and glucosuria (urinary excretion of glucose). Your doctor should monitor your condition and periodically check your glandular function if you are applying a large dose of any potent steroid preparation to a large area of your skin.
- Steroid medications such as Flutipro are more likely to cause side effects in children. Problems can include Cushing's syndrome and other adrenal problems, stunted growth, and high pressure inside the head. This excess pressure can lead to bulges in the skull, headaches, and eventually loss of vision.

Pregnancy and breastfeeding

Certain medicines should not be used during pregnancy or breastfeeding. However, other medicines may be safely used in pregnancy or breastfeeding providing the benefits to the mother outweigh the risks to the unborn baby. Always inform your doctor if you are pregnant or planning a pregnancy, before using any medicine.

- The effects of Cutivate during pregnancy have not been adequately studied. If you are pregnant or plan to become pregnant, inform your doctor immediately. It is not known whether Fluticasone propionate appears in breast milk. If Fluticasone propionate is essential to your health, your doctor may advise you to discontinue breastfeeding until your treatment is finished.

STORAGE:

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it in cool & dark place. DO NOT FREEZE.

Presentation

10 gm Tube

For further information, please contact:

Market Planning Department



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