

**Fluticasone propionate Cas No. : 80474-14-2**

This medication is a corticosteroid that works directly on the nasal passages to reduce swelling and inflammation. Fluticasone is used to relieve seasonal and year-round, allergic and non-allergic nasal symptoms such as itching, runny or stuffy nose, postnasal drip and sneezing in adults and children 4 years of age and older.

Active Pharmaceuticals Ingredients Manufacturers



Taj Pharma PDF

# Taj Pharmaceuticals Ltd.

## Fluticasone propionate

### CAS No. : 80474-14-2



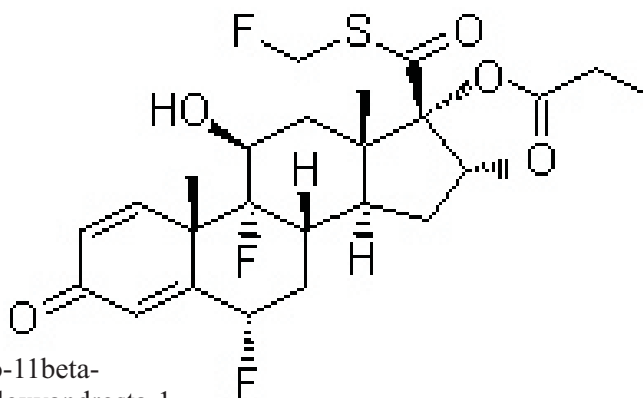
Molecular Weight 500.57  
CAS Registry Number 80474-14-2  
ATC code D07AC17 & D07AC04 (topical)  
PubChem 5311101  
DrugBank APRD00065  
ChemSpider 4470631

**Chemical data**

Formula C<sub>22</sub>H<sub>27</sub>F<sub>3</sub>O<sub>4</sub>S  
Mol. mass 444.508 g/mol  
SMILES eMolecules & PubChem

**Identification**

Synonyms S-Fluoromethyl-6alpha,9alpha-difluoro-11beta-hydroxy-16alpha-methyl-3-oxo-17alpha-propionyloxyandrost-1,4-diene-17beta-carbothioate; (6a,11b,16a,17a)-6,9-Difluoro-11-hydroxy-16-methyl-3-oxo-17-(1-oxopropoxy)androst-1,4-diene-17-carbothioic acid S-(fluoromethyl) ester

**Systematic (IUPAC) name**

S-(fluoromethyl) (6S,8S,9R,10S,11S,13S,14S,16R,17R)-6,9-difluoro-11,17-dihydroxy-10,13,16-trimethyl-3-oxo-6,7,8,11,12,14,15,16-octahydrocyclopenta[a]phenanthrene-17-carbothioate

**USES**

This medication is a corticosteroid that works directly on the nasal passages to reduce swelling and inflammation. Fluticasone is used to relieve seasonal and year-round, allergic and non-allergic nasal symptoms such as itching, runny or stuffy nose, postnasal drip and sneezing in adults and children 4 years of age and older.

**HOW TO USE**

Use this medication usually once or twice a day as directed by your doctor. Do not use more than 2 sprays in each nostril daily as this may increase the risk of side effects. Avoid spraying this medication in your eyes. Follow the detailed instructions for using the spray and cleaning the applicator. SIDE EFFECTS: Nasal dryness or irritation, nausea, vomiting, wheezing, or cough may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly

**PRECAUTIONS**

Before using fluticasone, tell your doctor or pharmacist if you are allergic to it, or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: recent nasal ulcers/trauma/surgery.



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**Fluticasone  
Propionate**  
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### MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

### STORAGE

Store at room temperature between 39-86 degrees F (4-30 degrees C) away from light. Do not store in the bathroom. Keep all medicines away from children and pets.

### DOSAGE

#### ADULTS

Apply a thin film of cream or ointment to the affected skin areas 1 or 2 times a day. Rub in gently. Contact your doctor if there is no improvement within 2 weeks.  
should not be used with tight, occlusive dressings or bandages.

#### CHILDREN

cream may be used with caution to treat children over 3 months of age. Apply a thin film of cream to the affected skin areas 1 or 2 times a day. Rub in gently. The safety of cream to treat children for longer than 4 weeks has not been established.

ointment is not recommended for use in children.  
should not be used with tight, occlusive dressings or bandages.

The safety and effectiveness of cream have not been established for treatments lasting more than 4 weeks in children or for infants below age 3 months.

ointment is not recommended for use in children.

### SIDE EFFECTS

Side effects cannot be anticipated. If any develop or change in intensity, inform your doctor as soon as possible

\* Burning, dryness, infected or worsening eczema, itchy spots, rash, skin irritation, stinging

Side effects occur more frequently with the use of airtight bandages. In children, the more likely side effects may include a burning sensation, hives, inflammation, rash, and red blotches on the face and body.

Do not use Fluticasone propionate for any disorder other than the one for which it was prescribed. Do not use cream on the face, underarms, or groin areas unless your doctor tells you to do so. Do not apply Cutivate if you have an infection in the affected skin 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 cream to the diaper area because covering a treated area with waterproof diapers or plastic pants can increase unwanted absorption

### PRECAUTIONS

Intranasal corticosteroids may cause a reduction in growth velocity when administered to pediatric patients. Rarely, immediate hypersensitivity reactions or contact dermatitis may occur after the administration. Rare instances of wheezing, nasal septum perforation, cataracts, glaucoma, and increased intraocular pressure have been reported following the intranasal application of corticosteroids, including fluticasone propionate. Use of excessive doses of corticosteroids may lead to signs or symptoms of hypercorticism and/or suppression of HPA function. Although systemic effects have been minimal with recommended doses, potential risk increases with larger doses. Therefore, larger than recommended doses should be avoided. When used at higher than recommended doses or in rare individuals at recommended doses, systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear. If such changes occur,



## INTERACTION

Fluticasone propionate is a substrate of cytochrome P450 3A4. A drug interaction study with fluticasone propionate in healthy subjects has shown that ritonavir (a highly potent cytochrome P450 3A4 inhibitor) can significantly increase plasma fluticasone propionate exposure, resulting in significantly reduced serum cortisol concentrations. During postmarketing use, there have been reports of clinically significant drug interactions in patients receiving fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects including Cushing syndrome and adrenal suppression. Therefore, coadministration of fluticasone propionate and ritonavir is not recommended unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side effects. In a placebo-controlled, crossover study in 8 healthy volunteers, coadministration of a single dose of orally inhaled fluticasone propionate (1,000 mcg; 5 times the maximum daily intranasal dose) with multiple doses of ketoconazole (200 mg) to steady state resulted in increased plasma fluticasone propionate exposure, a reduction in plasma cortisol AUC, and no effect on urinary excretion of cortisol.



## DRUG DESCRIPTION

Fluticasone is a synthetic steroid of the glucocorticoid family of drugs that is used for treating allergic conditions involving the nose. Fluticasone mimics the naturally-occurring hormone produced by the adrenal glands, cortisol or hydrocortisone. The exact mechanism of action of fluticasone is unknown. Fluticasone has potent anti-inflammatory actions. It is believed that fluticasone exerts its beneficial effects by inhibiting several types of cells and chemicals involved in allergic, immune and inflammatory responses. When used as a nasal inhaler or spray, the medication goes directly to the lining within the nose, and very little is absorbed into the rest of the body. Fluticasone propionate is a synthetic corticosteroid having the chemical name S-(fluoromethyl)6a,9-difluoro-11β-17-dihydroxy-16a-methyl-3-oxoandrosta-1,4-diene-17β-carbothioate, 17-propionate. Fluticasone propionate is a white to off-white powder.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs.

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:  
91 022 30601000.

This leaflet was prepared by  
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