Composition : **F-Pro Plus Nasal Spray :** Each Metered Spray Contains Azelastine Hydrochloride BP 137mcg (Eqv. to 125mcg Azelastine) & Fluticasone Propionate BP 50 mcg.

Pharmacology : Azelastine Hydrochloride exhibits histamine H1-receptor antagonist activity in isolated tissues. The major metabolite, desmethylazelastine, also possesses H1-receptor antagonist activity. Fluticasone Propionate is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. The precise mechanism through which Fluticasone Propionate affects allergic rhinitis symptoms is not known. Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g. mast cells, eosinophils, neutrophils, macrophages and lymphocytes etc.) and mediators (e.g. histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation.

Indications : Azelastine and Fluticasone Nasal Spray is indicated for the relief of symptoms of seasonal allergie rhinitis in patients 6 years of age and older who require treatment with both Azelastine Hydrochloride and Fluticasone Propionate for symptomatic relief.

Dosage & Administration : **Adult :** The recommended dosage is 1 spray each nostril twice daily. Or, as directed by the registered physicians.

Contraindications : There is no known contraindication.

Precautions : Engagement in hazardous occupations requiring complete mental alertness such as driving or operating machinery should be avoided when taking Azelastine and Fluticasone Nasal Spray. Concurrent use of alcohol or other central nervous system (CNS) depressants with this Nasal Spray should also be avoided because of further decreased alertness and impairment of CNS. Hypercorticism and adrenal suppression with very high dosages or at the regular dosage in susceptible individuals may appear. If such changes occur, the spray should be discontinued slowly.

Side effects : The most common adverse reactions are: dysgeusia, epistaxis, and headache.

F-Pro Plus

Nasal Spray

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Use in Pregnancy and Lactation : Pregnancy category C. There are no adequate and well-controlled clinical trials of Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray, Azelastine Hydrochloride only or Fluticasone Propionate only in pregnant women. It should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the fetus. **Nursing Mothers:** It is not known whether Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray is excreted in human breast milk. Because many drugs are excreted in human milk, caution should be exercised when administered to a nursing woman.

Use In Child : The safety and effectiveness of this Nasal Spray has not been established for patients less than 6 years of age.

Drug Interactions : Concomitant use of Potent inhibitors of cytochrome P450 (CYP) 3A4: May increase blood levels of fluticasone propionate. Ritanovir: Coadministration is not recommended. Other potent CYP3A4 inhibitors, such as ketoconazole: use caution with coadministration.

Overdose : There have been no reported over dosages with Azelastine Hydrochloride. Acute Azelastin Hydrochloride overdosage by adults with this dosage form is unlikely to result in clinically significant adverse events, other than increased somnolence. Chronic Fluticasone Propionate overdosage may result in symptoms of hypercorticism.

Storage : Store below 30°C protected from light. Keep out of the reach of children.

Packing : **F-Pro Plus Nasal Spray :** Each container contains 120 metered doses for spray.