

Cleaning your Nasal Spray

Your nasal spray should be cleaned at least once a week.

To do this:



Push the nozzle upwards to detach from the bottle.



Wash the nozzle and the dust cap in warm water.



Shake off excess water and allow nozzle and cap to dry at room temperature before refitting into the bottle.

Note:

If the nozzle becomes blocked, remove it as shown and soak in warm water. Rinse the nozzle under running cold water from a tap. Allow the nozzle to dry before refitting it to the bottle.

DO NOT USE A PIN OR A SHARP OBJECT TO UNBLOCK THE NOZZLE AS THIS WILL DESTROY THE SPRAY MECHANISM.

Storage:

Store below 30°C but do not refrigerate. Protect from light.

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Duonase - D

Each spray delivers

Azelastine Hydrochloride BP..... 140 mcg
Fluticasone propionate BP..... 50 mcg

Composition

Fluticasone propionate BP..... 0.0357%w/v
Azelastine Hydrochloride BP 0.10%w/v
Benzalkonium Chloride NF 0.01%w/v (as preservative)
Phenyl Ethyl alcohol USP 0.25%v/v (as preservative)

Description

Duonase - D is an antihistamine-corticosteroid combination available as a metered spray formulation for intranasal administration. It contains azelastine hydrochloride a second generation H₁ receptor antagonist with potent topical activity, and fluticasone propionate, a synthetic corticosteroid with anti-inflammatory properties.

Indications

Duonase - D Nasal Spray is indicated for the management of symptoms of allergic rhinitis, once the need for an antihistamine and corticosteroid has been established. It is recommended for the treatment of moderate to severe persistent symptoms in adults and adolescents above 12 years of age.

For children aged 5–12 years, **Duonase - D** Nasal Spray is recommended for severe symptoms of allergic rhinitis.

Duonase - D Nasal Spray can also be used for treating non-allergic vasomotor rhinitis in adults and adolescents, 12 years of age and older

Dosage and administration

Adults/Adolescents (Above 12 years of age) and Children (Aged 5 –12 years)

1 spray/nostril twice daily. The recommended dosage should not be exceeded. Not recommended for use in children below 5 years of age

Contraindications

Duonase - D Nasal Spray is contraindicated in patients with or known hypersensitivity to azelastine hydrochloride or fluticasone propionate or any of the components of the preparation.

Warnings and Precautions

- Concurrent use of this combination with alcohol or other CNS depressants or other antihistamines should be avoided as additional reductions in alertness and additional impairment of CNS performance may occur due to azelastine.

- The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency. Some patients may experience symptoms of withdrawal e.g. joint and/or muscular pain, lassitude and depression.

- The concomitant use of an intranasal corticosteroid with other corticosteroids could increase the risk of signs or symptoms of hypercorticism and/or suppression of the HPA-axis. Therefore such a combination should be used cautiously in patients with other pathological conditions requiring steroids.

- Intranasal corticosteroids may cause a reduction in growth velocity when administered at higher dose. The recommended dosage of **Duonase - D** Nasal Spray should not be exceeded.
- Special care is needed in patients with lung tuberculosis and fungal and viral infections. Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chicken pox and measles for example can have a more serious or even a fatal course in children on immunosuppressant corticosteroids.

- During long term therapy, monitoring of hematological and adrenal function is advisable.

- In clinical studies with intranasal fluticasone propionate, the development of localized infections of the nose and the pharynx caused by *Candida albicans* has been seen rarely. When such an infection develops, it may require treatment with appropriate local therapy and discontinuation of the treatment with **Duonase - D** Nasal Spray is advised.

Drug Interactions

The use of **Duonase - D** Nasal Spray in patients taking concurrent drugs that are potent inhibitors of the cytochrome 450 3A4 system, such as ketoconazole and protease inhibitors such as ritonavir, may be associated with increased systemic exposure of fluticasone.

Pregnancy and Lactation

The combination should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. It is not known whether azelastine hydrochloride or fluticasone propionate is excreted in human milk. Hence caution should be exercised while prescribing this combination to nursing mothers.

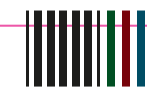
Side Effects

The most likely side effects with this combination are headache, somnolence, pharyngitis, epistaxis, nasal burning/irritation, nausea, vomiting, cough, taste disturbance. The combination may produce a bitter taste which may lead to occasional nausea. This bitter taste usually disappears after sometime.

Presentation

Duonase - D Sales pack contains 70 metered doses.

CR72 D



Patient Information Leaflet

Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray



70
METERED
DOSES

Before using your **Duonase - D** Nasal Spray read this leaflet carefully and follow the instructions.

Cipla

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Parts of the Nasal Spray



Using your Nasal spray correctly

Before use:



Shake the bottle gently and then remove the protective dust cap.



Hold the bottle as shown with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle.



If using for the first time or if you have not used it for a week or more, test the spray: with the nozzle pointing away from you, press down several times as shown until a fine mist comes out of the nozzle.

During use:



Blow your nose gently.



Close one nostril as shown and put the nozzle in the other nostril.

6 Start to breathe in through your nose and **WHILE BREATHING IN** press down with your fingers **ONCE** to release a spray.



Breathe out through your mouth. Repeat steps 6 and 7 to inhale a second spray.

8 Repeat steps 5, 6 and 7 for the other nostril.

After use



Wipe the nozzle with a clean handkerchief / tissue and replace the protective dust cap.

