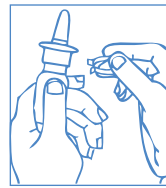
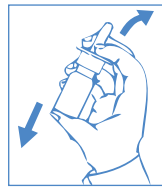


Parts of the device

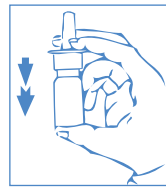
1. Plastic container
2. Metered valve
3. Nasal applicator
4. Dust cap
5. Safety clip



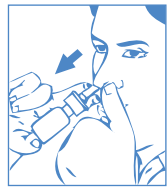
Pic-1



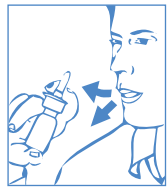
Pic-2



Pic-3



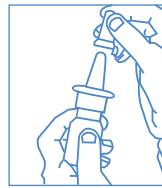
Pic-4



Pic-5



Pic-6



Pic-7

Please read this part before you start using your Nasal Spray

Before using:

1. At first, remove the safety clip. (Pic-1)
2. Shake the bottle gently, then remove the dust cap. (Pic-2)
3. Hold the bottle (as shown) with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle. (Pic-2)
4. Before using your Nasal Spray for the first time, or if you have not used it for a longer period, follow the instructions given below.

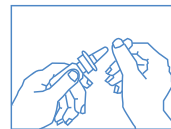
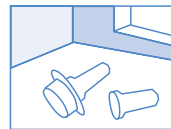
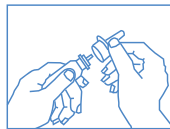
With the nozzle pointing away from you, press several times as shown until a fine uniform mist comes out of the nozzle. (Pic-3)

5. Blow your nose gently.
6. Close one nostril and put the nozzle in other nostril as shown. Tilt your head slightly forward keeping the nozzle in the upright position. (Pic-4)
7. Start to breathe in through your nose and while breathing in, press down with your fingers once to release a spray. (Pic-4)
8. Breathe out through your mouth. Repeat steps 7 and 8 to have a second spray. (Pic-5)
9. Repeat steps 6, 7 and 8 for the other nostril. (Pic-6)
10. After use: Wipe the nozzle with a clean cloth and replace the dust cap. (Pic-7)

Note:

The first time you use Nasal Spray, you may sneeze a few times. This is because the lining of your nose is very sensitive. This is not likely to happen after the first few dose.

This medication can, at times cause, a few side effects in certain hypersensitive individuals. If you notice any bleeding from your nose or experience any other discomfort, please inform your doctor.



Cleansing:

Your Nasal Spray should be cleaned at least once a week.

1. Push the nozzle upwards to detach from the bottle.
2. Wash the nozzle and dust cap in warm water. Shake off excess water and leave to dry in a warm place. Avoid excessive heat.
3. Replace the nozzle and dust cap.
4. If the nozzle becomes blocked, remove it and soak in warm water. Rinse under a cold tap. Allow to dry and refit.

Do not use a pin or other sharp objects to unblock the nozzle.

Dynase®

Azelastine hydrochloride 137 µg and Fluticasone propionate 50 µg Nasal Spray

Description

Dynase® (azelastine hydrochloride and fluticasone propionate) Nasal Spray is formulated as a uniform metered-spray suspension for intranasal administration. It is a fixed dose combination product containing an antihistamine (H1 receptor antagonist) and a corticosteroid as active ingredients.

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 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) and mediators (e.g., histamine, eicosanoids, leukotrienes and cytokines) involved in inflammation.

Indications

Relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.

Dosage and Administration

Adults and adolescents (12 years and older): One actuation in each nostril twice daily (morning and evening).

It is not recommended for use in children below 12 years of age as safety and efficacy has not been established in this age group.

Use in Specific Populations

Fertility

There are only limited data with regard to fertility.

Pregnancy

There are no or limited amount of data from the use of Azelastine hydrochloride and Fluticasone propionate in pregnant women. Therefore, it should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Lactation

It is unknown whether nasally administered Azelastine hydrochloride/metabolites or Fluticasone propionate/metabolites are excreted in human breast milk. It should be used during lactation only if the potential benefit justifies the potential risk to the new-borns/infant.

Side Effects

The most common adverse reactions (≥2% incidence) are: dysgeusia, epistaxis and headache.

Contraindication

Hypersensitivity to the active substances.

Warning & Precaution

Engagement in hazardous occupations requiring complete mental alertness such as driving or operating machinery should be avoided when taking this medication. 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, contact with physician and

discontinue the spray slowly overtime.

Drug Interactions

Ritonavir can greatly increase fluticasone propionate plasma concentrations, resulting in markedly reduced serum cortisol concentrations. During post marketing use, there have been reports of clinically significant drug interactions in patients receiving intranasal or inhaled Fluticasone propionate and Ritonavir, resulting in systemic corticosteroid effects. Co-treatment with other CYP 3A4 inhibitors, including cobicistat-containing products is also expected to increase the risk of systemic side effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side effects.

Studies have shown that other inhibitors of cytochrome P450 3A4 produce negligible (Erythromycin) and minor (Ketoconazole) increases in systemic exposure to fluticasone propionate without notable reductions in serum cortisol concentrations. Nevertheless, care is advised when co-administering potent cytochrome P450 3A4 inhibitors (e.g. ketoconazole), as there is potential for increased systemic exposure to Fluticasone propionate.

No specific interaction studies with Azelastine hydrochloride nasal spray have been performed. Nevertheless, care should be taken when administering Azelastine hydrochloride in patients taking concurrent sedative or central nervous medications because sedative effect may be enhanced. Alcohol may also enhance this effect.

Overdose

There have been no reported over dosages with Azelastine hydrochloride. Acute Azelastine 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

Do not store above 30° C. Keep in a dry place. Protect from light. Keep out of the reach of children.

Commercial Pack

Dynase® Nasal Spray: Each bottle contains 120 metered sprays. Each actuation delivers Azelastine hydrochloride USP 137 µg (equivalent to Azelastine 125 µg) and Fluticasone propionate BP 50 µg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

126, Kathaldia, Auchpara, Tongi, Gazipur, Bangladesh

3020006375 121119

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Note for users

1. Use your Nasal spray as directed by your physician. Do not exceed the recommended dose.
2. This medicine has been specially recommended by your physician for you. Do not allow any other person to use it.
3. Use within two months of opening.

