



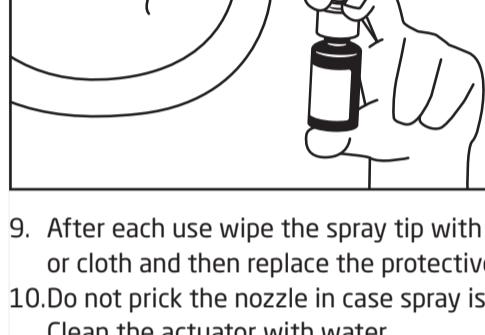
2. Blow your nose to clear your nostrils.
3. Keep your head tilted downwards towards your toes. Do not tilt head backwards.
4. Hold the bottle upright and carefully insert the spray tip into one nostril.
5. Close other nostril with your finger, rapidly press down once and sniff gently at the same time (see figure 3).
6. Breathe out through your mouth.

Figure 3



7. Repeat in your other nostril.
8. Breathe in gently, and do not tilt your head back after dosing. This will stop the medicine going into your throat and causing an unpleasant taste (see figure 4).

Figure 4



9. After each use wipe the spray tip with a clean tissue or cloth and then replace the protective cap.
10. Do not prick the nozzle in case spray is not obtained. Clean the actuator with water.

It is important that you take your dose as advised by your doctor. You should use only as much as your doctor recommends.

#### Duration of treatment

This medicine is suitable for long-term use. The duration of treatment should correspond to the period of experiencing allergy symptoms.

#### If you use more Azelastine Hydrochloride/Fluticasone Propionate Nasal Spray than you should

If you spray too much of this medicine into your nose you are unlikely to have any problems.

If you are worried or if you have used doses higher than recommended over a long period, contact your doctor. If anyone, especially a child, accidentally drinks this medicine, contact your doctor or nearest hospital casualty department as soon as possible.

#### If you forget to use Azelastine Hydrochloride/Fluticasone Propionate Nasal Spray

Use your nasal spray as soon as you remember, then take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

#### If you stop using Azelastine Hydrochloride/Fluticasone Propionate Nasal Spray

Do not stop using this medicine without asking your doctor, because this puts the success of the treatment at risk.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### Very common (may affect more than 1 in 10 people):

- nosebleed.

#### Common (may affect up to 1 in 10 people):

- headache
- a bitter taste in your mouth, especially if you tilt your head backwards when you are using the nasal spray. This should go away if you have a soft drink a few minutes after using this medicine.
- unpleasant smell.

#### Uncommon (may affect up to 1 in 100 people):

- slight irritation of the inside of the nose. This can cause mild stinging, itching or sneezing.
- nasal dryness, cough, dry throat or throat irritation.

#### Rare (may affect up to 1 in 1,000 people):

- dry mouth.

#### Very rare (may affect up to 1 in 10,000 people):

- dizziness or drowsiness

• cataract, glaucoma or increased pressure in your eye where you may have a loss of vision and/or red and painful eyes. These side effects have been reported following prolonged treatment with fluticasone propionate nasal sprays.

• damage of the skin and mucous membrane in the nose

• feeling sick, weary, exhausted or weak

• rash, itchy skin or red, raised itchy bumps

• bronchospasm (the narrowing of the airways in the lungs).

#### Seek immediate medical help if you have any of the following symptoms:

- **Swelling of face, lips, tongue or throat which may cause difficulty in swallowing/breathing and a sudden onset of skin rash.** This could be signs of a severe allergic reaction. **Please note: This is very rare.**

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#### Side effects with unknown frequency (frequency cannot be estimated from available data):

- blurred vision
- sores in the nose.

Systemic side effects (side effects concerning the whole body) may occur when this medicine is used at high doses for a long time. These effects are much less likely to occur if you use a corticosteroid nasal spray than if you take corticosteroids by mouth. These effects may vary in individual patients and between different corticosteroid preparations (see section 2).

Nasal corticosteroids can affect the normal production of hormones in your body, particularly if you use high doses for a long time. In children and adolescents this side effect can cause them to grow more slowly than others.

In rare cases a reduction of the bone density (osteoporosis) was observed, if nasal corticosteroids were administered long-term.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Azelastine Hydrochloride/Fluticasone Propionate Nasal Spray

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and the carton after "EXP". The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

Shelf life after first opening: Dispose of any unused medicine 6 months after you first open the nasal spray.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

#### What Azelastine Hydrochloride/Fluticasone Propionate Nasal Spray contains

The active substances are azelastine hydrochloride and fluticasone propionate.

Each ml of suspension contains 1000 micrograms azelastine hydrochloride and 365 micrograms fluticasone propionate.

Each actuation (0.14 g) delivers 137 micrograms azelastine hydrochloride (equivalent to 125 micrograms azelastine) and 50 micrograms fluticasone propionate.

The other ingredients are disodium edetate, glycerol (E422), microcrystalline cellulose, carmellose sodium, polysorbate 80, benzalkonium chloride, phenylethyl alcohol and water for injections.

#### What Azelastine Hydrochloride/Fluticasone Propionate Nasal Spray looks like and contents of the pack

Azelastine Hydrochloride/Fluticasone Propionate Nasal Spray, Suspension is a white nasal spray, suspension in an amber coloured glass bottle fitted with a spray pump, applicator and a protective cap.

Each bottle contains 23 g nasal spray, suspension in 25 ml bottles (at least 120 actuations).

Each pack contains 1 bottle with 23 g nasal spray, suspension or multipacks containing 3 bottles, each containing 23 g nasal spray suspension.

Not all pack sizes may be marketed.

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#### Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

#### Manufacturer

Teva Czech Industries s.r.o., Ostravská 305/29, 747 70

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