Histoleve Plus+

azelastine hydrochloride/fluticasone propionate nasal spray
137 micrograms per spray / 50 micrograms per spray

Consumer Medicine Information (CMI)

Please read this leaflet carefully before you start using Histoleve Plus+.

This leaflet answers some common questions about Histoleve Plus+. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

1. What is Histoleve Plus+ used for?

Histoleve Plus+ nasal spray relieves the symptoms of allergies, for example: symptoms relating to the nose - runny nose, post-nasal drip, sneezing, itchy or blocked nose and symptoms relating to the eyes - itchy, watery and red eyes.

Due to the fast relief and the anti-inflammatory effect, Histoleve Plus+ nasal spray is more effective on symptoms relating to the nose and eyes than either antihistamine or corticosteroid therapy alone.

Histoleve Plus+ is sprayed into the nose to treat allergic rhinitis (hay fever and other allergies) and rhino conjunctivitis (allergy-induced symptoms in the nose and eyes) in adults and children 12 years and older where use of a combination (intranasal antihistamine and glucocorticoid) is appropriate.

Hay fever is an inflammation or swelling of the nose lining (which may cause blockage, runny nose, itching and/or sneezing).

You may have symptoms only during spring or summer. This type of allergy is generally due to various pollens. Some people may experience symptoms all year round. This is usually caused by house dust mites, pets or moulds.

This medicine contains two active ingredients: azelastine hydrochloride and fluticasone propionate.

Azelastine hydrochloride belongs to a group of medicines called antihistamines. Antihistamines work by preventing the effects of substances such as histamine that the body produces as part of an allergic reaction. This reduces symptoms of allergic rhinitis.

Fluticasone propionate belongs to a group of medicines called corticosteroids which are used to help reduce inflammation.

This medicine is available from pharmacies without a prescription.

2. Before you start to use Histoleve Plus+?

Warnings

- Do not use the medicine if you have an allergy to azelastine hydrochloride or fluticasone propionate or any of the other ingredients listed at the end of this leaflet.
  Some of the symptoms of an allergic reaction to a medicine may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- Do not give this medicine to a child under the age of 12 years.
- Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor or pharmacist if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
  - recent injury or surgery to your nose or mouth
  - infection in your nose or sinus
  - ulcer or open sores in your nose
  - active or inactive tuberculosis
  - severe liver disease
  - increased/ high pressure in the eye (glaucoma) and/ or cataracts
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant. Your pharmacist or doctor can discuss with you the risks and benefits involved. If you become pregnant while you are using this medicine, tell your doctor or pharmacist.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed. It is not known if Histoleve Plus+ passes into the breast milk and could affect your baby. Your pharmacist or doctor can discuss with you the benefits and risks involved with using this medicine while you are breastfeeding.

3. Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your pharmacist or doctor if you are taking**:**

- a medicine or medicines that depress the central nervous system. Concurrent use with Histoleve Plus+ may cause sleepiness or drowsiness.
- ritonavir, an antiviral medicine.
- ketoconazole, an antifungal medicine.
- cimetidine, a medicine that inhibits stomach acid production.

These medicines may be affected by Histoleve Plus+ or may affect how well it works. You may need different amounts of your medicine, or you may need to use a different medicine. Your healthcare professional will advise you.

Do not use Histoleve Plus+ with another steroid product, e.g. tablets, asthma or nasal inhaler, except on the advice of your healthcare professional.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

4. How to use Histoleve Plus+?

Use only in your nose. Do not spray Histoleve Plus+ in your eyes.

Start using this medicine early to help reduce the severity of your symptoms:

- before the hay fever season, or
- before coming in contact with something you know will cause your hay fever.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

5-steps to use

Before you use Histoleve Plus+ nasal spray for the first time, you will need to prime the bottle.

1. **Shake:** Before you prime the bottle, shake it gently. Remove the clear plastic dust cap from the spray pump tip of the bottle.
2. **Prime:** Hold bottle upright with 2 fingers on the shoulders of the spray pump and your thumb on the bottom of the bottle. Press upward with your thumb and release. Repeat pumping action. Pump bottle 6 times. Once you see a fine mist, your Histoleve Plus+ nasal spray is ready to use.
3. **Clear:** Blow your nose to clear nostrils. Shake the bottle gently.
4. **Insert:** Close one nostril with a finger. Place spray pump tip just into your other nostril. Tilt head forward slightly so chin rests on chest and open mouth. Do not tilt head back. Do not spray directly onto the nasal septum (the wall between your 2 nostrils).
5. **Spray and breathe:** Keeping bottle upright and mouth open, pump once gently. As you spray, breathe in lightly through the treated nostril. Repeat in other nostril. Wipe off the tip with clean tissue. Replace dust cap.

If you do not use your spray for 7 or more days, you'll need to prime the pump with 1 spray, or until you see a fine mist. If you do not see a fine mist, clean the tip of the spray nozzle (see Cleaning instructions).

How much to use

Adults and children 12 years and older: One spray into each nostril in the morning and evening.

Do not use in children under 12 years.

Do not exceed the maximum dose.

Dose should be reduced for maintenance treatment once full effect is obtained.

How long to use

Do not use Histoleve Plus+ for longer than six months except on the advice of a doctor or pharmacist.

If you forget to use

If you miss a dose, use Histoleve Plus+ when the next dose is due.

Do not use a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you or someone else accidentally uses too much Histoleve Plus+ on one occasion, there is nothing to worry about.

However, if you use too much of it over a long time (months or years), you may start to get unwanted side effects inside your nose and body.

Discuss any worries you may have about this with your doctor or pharmacist.

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 764766) if you or anyone else may have accidentally swallowed Histoleve Plus+ nasal spray. Do this even if there are no signs or symptoms of discomfort or poisoning.

5. While you are using Histoleve Plus+?

Things you should do

- If possible, avoid situations that you know will trigger your symptoms.
- Consult your doctor or pharmacist if the symptoms/ condition persist(s) for more than 7 days.

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using this medicine.
- Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.
- Consult your doctor or pharmacist if you develop signs/symptoms of nasal infection such as fever, facial pain or swelling, or discoloured nasal discharge.
- Consult your doctor or pharmacist if your nose bleeds.

Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.
- Do not use it to treat any other complaints unless your doctor or pharmacist tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Histoleve Plus+ affects you.

Histoleve Plus+ is unlikely to make you feel drowsy. However, if you are drowsy, do not drive a car or operate machinery, or do anything else that could be dangerous if you are tired, drowsy, dizzy or light-headed.

Storage

- Keep Histoleve Plus+ in a place where the temperature stays at or below 25 °C. Do not refrigerate or freeze this medicine.
- Discard after 6 months of first opening the bottle.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Cleaning instructions

1. Once a week, remove the dust cap. Gently pull upward on the spray pump to lift away from the bottle.
2. Wash the dust cap and spray pump in warm tap water.
3. Allow to dry completely. When dry, place the spray pump and dust cap back on the bottle. Re-prime the pump before using Histoleve Plus+ again.
4. If pump is blocked:
    - Soak in warm water.
    - After the pump is unblocked, rinse with cold water.
    - Allow to dry.
    - Replace dust cap.
    - Do not try to unblock pump with a sharp object. This can damage the spray pump and cause you to not get the right dose of medicine.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Histoleve Plus+.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Irritated nose (This can cause mild stinging, itching or sneezing.)
- cough, dry throat or throat irritation
- sore throat
- nose bleeds
- nausea
- headache

If you get a bitter taste in your mouth, it may be the way you are spraying; please check steps 4 & 5 again. If this continues, please tell your pharmacist or doctor.

Consult a healthcare professional if you notice any of the following:

- sleepiness or drowsiness
- feeling weary, exhausted or weak
- damage of the skin and mucous membrane in the nose
- blurred vision, eye pain or increased pressure in your eye

If any of the following happen, stop using Histoleve Plus+ and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems (for Australia) and https://pophealth.my.site.com/carmreportnz/s/ (for New Zealand). By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Histoleve Plus+ contains

Active ingredient (main ingredient)	• azelastine hydrochloride • fluticasone propionate
Other ingredients (inactive ingredients)	dispersible cellulose glycerol polysorbate 80 disodium edetate benzalkonium chloride phenylethyl alcohol purified water

Do not take this medicine if you are allergic to any of these ingredients.

What Histoleve Plus+ looks like

Histoleve Plus+ Nasal Spray is a fixed combination product containing azelastine hydrochloride and fluticasone propionate in a suitable liquid kept in a glass bottle with metered-dose manual pump.

Who distributes Histoleve Plus+

AFT Pharmaceuticals Ltd.
Auckland, New Zealand

Email: customer.service@aftpharm.com

This leaflet was prepared on 17 September 2026