

PATIENT INFORMATION LEAFLET FOR

CIPZAMIST

SCHEDULING STATUS: S2

CIPZAMIST (137 µg / 50 µg per actuation

nasal spray, suspension)

Azelastine hydrochloride/ Fluticasone propionate

Sugar free

Read all of this leaflet carefully before you start using CIPZAMIST

Keep this leaflet. You may need to read it again.

- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. (See **section 4**)
- CIPZAMIST has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CIPZAMIST is and what it is used for
2. What you need to know before you take CIPZAMIST
3. How to take CIPZAMIST
4. Possible side effects
5. How to store CIPZAMIST
6. Contents of the pack and other information.

1. What CIPZAMIST is and what it is used for

CIPZAMIST contains two active substances: 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 – thus reducing symptoms of allergic rhinitis.
- Fluticasone propionate belongs to a group of medicines called corticosteroids which reduces inflammation.

CIPZAMIST is used to treat the symptoms of moderate to severe seasonal and perennial allergic rhinitis if the use of either intranasal antihistamine or corticosteroid alone is not considered sufficient.

CIPZAMIST is also used to treat symptoms of seasonal allergic rhinitis in children 6 years of age and older.

Seasonal and perennial allergic rhinitis are allergic reactions to substances such as pollen (hay fever), house mites, moulds, dust, or pets.

CIPZAMIST relieves the symptoms of allergies, for example: runny nose, postnasal drip, sneezing and itchy or blocked nose.

2. What you need to know before you take CIPZAMIST

Do not take CIPZAMIST if you:

- are hypersensitive (allergic) to azelastine hydrochloride or fluticasone propionate or any of the other ingredients of CIPZAMIST (listed in **Section 6**).

Warnings and Precautions

Tell your doctor or health care provider before using CIPZAMIST if:

- You had a recent operation on your nose.
- You have an infection in your nose. Infections of the nasal airways should be treated with antibacterial or antifungal medication. If you are given medication for an infection in your nose you can continue to use CIPZAMIST to treat your allergies.
- You have tuberculosis or an untreated infection.
- You have a change in vision or a history of increased ocular pressure, glaucoma and/or cataracts.
- You suffer from impaired adrenal function. Care must be taken when transferring from systemic steroid treatment to CIPZAMIST.
- You suffer from a severe liver disease. Your risk of suffering from systemic side effects is increased.
- You are using HIV medication named ritonavir.

In these cases, your doctor will decide whether you can use CIPZAMIST.

It is important that you take your dose as stated in **section 3** below or as recommended by your doctor. Treatment with higher than recommended doses of nasal corticosteroids may result in adrenal suppression, a condition that may produce weight loss, fatigue, muscle weakness, low blood sugar, salt cravings, joint pains, depression and darkening of the skin. If this happens your doctor may recommend another medicine during periods of stress or elective surgery.

To avoid adrenal suppression your doctor will advise you to take the lowest dose at which effective control of your symptoms of rhinitis is maintained.

Taking nasal corticosteroids (as contained in CIPZAMIST) may when taken for a long time cause children and adolescents to grow more slowly. The doctor will check your child's height regularly, and make sure he or she is taking the lowest possible effective dose.

Contact your doctor if you experience blurred vision or other visual disturbances.

If you are unsure whether the above applies to you, talk to your doctor or pharmacist before Using CIPZAMIST.

Children and adolescents

This medicine is not recommended for children under 6 years.

Other medicines and CIPZAMIST

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Some medicines may increase the effects of CIPZAMIST and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV e.g., ritonavir, cobicistat; and medicines for the treatment of fungal infections e.g., ketoconazole).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking CIPZAMIST.

Driving and using machinery

CIPZAMIST has minor influence on the ability to drive and use machines.

Very rarely, you may experience fatigue or dizziness due to the disease itself or when using CIPZAMIST. In these cases, do not drive or operate machinery. Please be aware that drinking alcohol may enhance these effects.

CIPZAMIST contains benzalkonium Chloride

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

Tell your doctor or pharmacist if you feel discomfort when using the spray.

3. How to use CIPZAMIST

Do not share medicines prescribed for you with any other person.

Always use CIPZAMIST exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with CIPZAMIST will last.

If you have the impression that the effect of CIPZAMIST is too strong or too weak, tell your doctor or pharmacist.

It is essential to use CIPZAMIST regularly to gain the full therapeutic benefit.

Contact with the eyes should be avoided.

Adults and children 6 years and older

The recommended dose is one spray into each nostril in the morning and evening.

Use in children under 6 years

This medicine is not recommended for children under 6 years.

Duration of treatment

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

Use in renal and hepatic impairment

There are no data in patients with renal and hepatic impairment.

Method of administration

CIPZAMIST is for nasal use only.

Read the following instructions carefully and use only as directed.

INSTRUCTION FOR USE

Preparing the spray

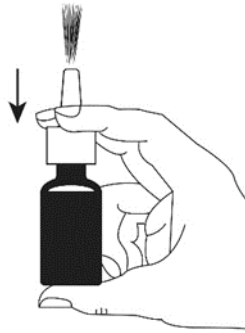
1. Shake the bottle gently for 5 seconds by tilting it upwards and downwards and then remove the protective cap (see figure 1).

Figure 1



2. The first time the nasal spray is used, you must prime the pump by squirting it into the air.
3. Prime the pump by putting two fingers on either side of the spray pump and place your thumb on the bottom of the bottle.
4. Press down and release the pump 6 times until a fine mist appears (see figure 2).
5. Now your pump is primed and ready to use.

Figure 2



6. If the nasal spray has not been used for more than 7 days, you will need to re-prime the pump once by pressing down and releasing the pump.

Using the spray

1. Shake the bottle gently for 5 seconds by tilting it upwards and downwards and then remove the protective cap (see figure 1).
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.

If you take more CIPZAMIST 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 CIPZAMIST, contact your doctor or nearest hospital casualty department as soon as possible.

If you forget to take CIPZAMIST

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.

Effects when treatment with CIPZAMIST is stopped

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

4. Possible Side Effects

CIPZAMIST can have side effects.

Not all side effects reported for CIPZAMIST are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CIPZAMIST, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking CIPZAMIST and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,

- rash, itchy skin or red, raised itchy bumps.

These are all very serious side effects. If you have them, you may have had a serious reaction to CIPZAMIST. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- tightness of the chest, or wheezing.
- systemic side effects (side effects concerning the whole body) may occur when CIPZAMIST 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. 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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache.
- nosebleed, which are more likely to occur if you use CIPZAMIST for more than 6 weeks continuously.

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

Less frequent side effects:

- pain, burning, irritation, soreness, or dryness inside the nose, or scabbing and crusting with small holes (perforations) in the ridge inside the nose that separates the nostrils.
- feeling sick, weary, exhausted or weak.
- dry mouth.
- 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.
- dizziness or drowsiness.

Side effects with unknown frequency:

- blurred vision.
- sores in the nose.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or by e-mail: drugsafetysa@cipla.com

or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of CIPZAMIST.

5. How to store CIPZAMIST

Store all medicines out of reach of children.

Store at or below 30 °C. Do not freeze or refrigerate.

Dispose of any unused medicine 6 months after you first open the nasal spray.

Keep the container in the outer carton.

Do not use after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What CIPZAMIST contains

The active substances are: azelastine hydrochloride and fluticasone propionate. Each gram of suspension contains 1000 µg azelastine hydrochloride equivalent to 913 µg azelastine and 365 µg fluticasone propionate.

Each actuation (0,14 g) delivers 137 µg azelastine hydrochloride (= 125 µg azelastine) and 50 µg fluticasone propionate.

The other ingredients are: glycerol, microcrystalline cellulose, carmellose sodium, disodium edetate, polysorbate 80, benzalkonium chloride, phenylethyl alcohol and purified water.

What CIPZAMIST looks like and contents of the pack

CIPZAMIST Nasal spray, suspension. A white, homogenous suspension.

CIPZAMIST Nasal spray comes in an amber glass bottle fitted with a spray pump, a nasal applicator and a dust cap.

The 25 mL bottle contains 23 g nasal spray, suspension (at least 120 actuations).

CIPZAMIST Nasal Spray is presented in:

Single packs containing 1 bottle with 23 g nasal spray, suspension (contains at least 120 actuations).

Multipacks containing 69 g (3 bottles with 23 g each) nasal spray, suspension.

The bottles are packed in carton boxes.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

This leaflet was revised in

First authorisation: 15 April 2025

Revision: Not applicable

Registration number

57/21.5.1/0333

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.
--