MISTY-DUO® ALLERGY

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using MISTY-DUO ALLERGY?

MISTY-DUO ALLERGY contains the active ingredients azelastine (as hydrochloride) and fluticasone propionate. MISTY-DUO ALLERGY is used to treat moderate and severe allergic rhinitis (hayfever). It relieves sneezing and runny, itchy or blocked nose.

For more information, see Section 1. Why am I using MISTY-DUO ALLERGY? in the full CMI.

2. What should I know before I use MISTY-DUO ALLERGY?

Do not use if you have ever had an allergic reaction to azelastine (as hydrochloride) or fluticasone propionate or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use MISTY-DUO ALLERGY? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MISTY-DUO ALLERGY and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use MISTY-DUO ALLERGY?

- Spray one spray into each nostril in the morning and evening. Adolescents from 12 – 17 years of age should only use this medicine on advice from a doctor. This medicine is not recommended for children under 12 years of age.

More instructions can be found in Section 4. How do I use MISTY-DUO ALLERGY? in the full CMI.

5. What should I know while using MISTY-DUO ALLERGY?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are

	using MISTY-DUO ALLERGY.
Things you should not do	• If you miss a dose, do not use a double dose to make up for the dose that you missed. • MISTY-DUO ALLERGY should not be used for more than 6 months.
Driving or using machines	• MISTY-DUO ALLERGY is unlikely to make you feel drowsy. However, if you are drowsy, do not drive a car or operate machinery. Alcohol may make drowsiness worse.
Looking after your medicine	• Keep MISTY-DUO ALLERGY in a cool dry place where the temperature stays below 25°C. Do not refrigerate or freeze this medicine. • Discard MISTY-DUO ALLERGY after 6 months of first opening the bottle.

For more information, see Section 5. What should I know while using MISTY-DUO ALLERGY? in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur. The most common and serious side effects are irritated nose (can cause mild stinging, itching or sneezing), a bitter or unpleasant taste in your mouth, unpleasant smell, cough, dry throat or throat irritation, sore throat, nose bleeds, nausea and headache.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

MISTY-DUO® ALLERGY

Active ingredient(s): *azelastine (as hydrochloride)/ fluticasone propionate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MISTY-DUO ALLERGY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MISTY-DUO ALLERGY.**

Where to find information in this leaflet:

1. Why am I using MISTY-DUO ALLERGY?
2. What should I know before I use MISTY-DUO ALLERGY?
3. What if I am taking other medicines?
4. How do I use MISTY-DUO ALLERGY?
5. What should I know while using MISTY-DUO ALLERGY?
6. Are there any side effects?
7. Product details

1. Why am I using MISTY-DUO ALLERGY?

MISTY-DUO ALLERGY contains the active ingredients azelastine (as 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 the symptoms of allergic rhinitis.

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

MISTY-DUO ALLERGY is used to treat moderate to severe allergic rhinitis (hayfever and other allergies) in adults and children 12 years and older for up to 6 months. MISTY-DUO ALLERGY should only be used by adolescents from 12 – 17 years on advice of a doctor.

MISTY-DUO ALLERGY relieves sneezing and runny, itchy or blocked nose.

Hayfever 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.

2. What should I know before I use MISTY-DUO ALLERGY?

Warnings

Do not use MISTY-DUO ALLERGY if:

- you are allergic to azelastine hydrochloride or fluticasone propionate, or any of the ingredients listed at the end of this leaflet.
- this medicine has expired or if the tamper evident packaging is damaged.

Check with your doctor or pharmacist if you:

- have any other 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
- have allergies to any other medicine, foods, preservatives or dyes.

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.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

It is not known if MISTY-DUO ALLERGY passes into the breast milk and could affect your baby. Your doctor or pharmacist can discuss with you the benefits and risks involved with using this medicine while you are breastfeeding.

MISTY-DUO ALLERGY Nasal Spray contains benzalkonium chloride.

MISTY-DUO ALLERGY Nasal Spray contains 14 micrograms (equiv. to 0.014mg or 0.14g) benzalkonium chloride in each spray. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. What if I am 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.

Some medicines may interfere with MISTY-DUO ALLERGY and affect how it works.

In particular, tell your doctor if you are taking:

- A medicine or medicines that depress the central nervous system. Concurrent use with MISTY-DUO ALLERGY 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 MISTY-DUO ALLERGY 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 doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MISTY-DUO ALLERGY.

4. How do I use MISTY-DUO ALLERGY?

How much to use

Adults and adolescents (12 years and older)

- One spray into each nostril in the morning and evening.
- Adolescents from 12 – 17 years should only use MISTY-DUO ALLERGY on advice from a doctor.

Children under 12 years

- This medicine is not recommended for children under 12 years.

When to use MISTY-DUO ALLERGY

MISTY-DUO ALLERGY should not be used for more than 6 months except on the advice of a doctor.

How to use MISTY-DUO ALLERGY

Only use in your nose.

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

Preparing the spray

1. Gently blow your nose before using the medicine.
2. Shake the bottle for 5 seconds and then remove the protective cap.
3. The first time MISTY-DUO ALLERGY is used, prime the pump by squirting it into the air.

4. Prime the pump by putting two fingers on either side of the spray pump and place your thumb on the bottom of the bottle.
5. Press down and release the pump 6 times until a fine mist appears.
6. The pump is now primed and ready to use.
7. If the nasal spray has not been used for more than 7 days, you will need to prime the pump until a fine mist appears again.

Using the spray

1. Blow your nose to clear your nostrils.
2. Keep your head tilted downwards towards your toes. Do not tilt head backwards.
3. Hold the bottle upright and carefully insert the spray tip into one nostril.
4. Close other nostril with your finger, rapidly press down once and sniff gently at the same time.
5. Breathe out through your mouth.
6. Repeat in your other nostril.
7. 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.
8. After each use, wipe the spray tip with a clean tissue or cloth and then replace the protective cap.

Use MISTY-DUO ALLERGY Nasal Spray regularly

It is important that you use MISTY-DUO ALLERGY Nasal Spray regularly. While the effect of the antihistamine (azelastine hydrochloride) is rapid, it may take several days for the full anti-inflammatory action (from fluticasone propionate) to take effect. Taking it regularly will help prevent your symptoms returning quickly.

If you forget to use MISTY-DUO ALLERGY

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

Always use MISTY-DUO ALLERGY exactly as described in this leaflet or how your pharmacist or doctor has told you.

If you use too much MISTY-DUO ALLERGY

If you think that you have used too much MISTY-DUO ALLERGY 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.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MISTY-DUO ALLERGY?

Things you must do

If you become pregnant while you are using this medicine, tell your doctor.

Your doctor can discuss with you the risks of using it while you are pregnant.

Remind any doctor, dentist or pharmacist you visit that you are using MISTY-DUO ALLERGY.

See your doctor or pharmacist if

- Symptoms are not relieved within 7 days
- Your nose bleeds
- You develop signs or symptoms of a nasal or sinus infection such as fever, pain or swelling, or discoloured nasal discharge

- You have eye pain or visual disturbance

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 tells you to.
- Do not give this medicine to a child under the age of 12 years.
- Do not give this medicine to adolescents aged 12 – 17 years unless advised by a doctor.
- Do not exceed the recommended dose.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MISTY-DUO ALLERGY affects you.

MISTY-DUO ALLERGY is unlikely to make you feel drowsy. However, if you are tired, drowsy, dizzy or lightheaded, do not drive a car or operate machinery. Alcohol intake may make drowsiness worse.

Looking after your medicine

- Keep MISTY-DUO ALLERGY in a cool dry place where the temperature stays below 25°C.
- Do not refrigerate or freeze this medicine.

Follow the instructions in the carton on how to take care of your medicine properly.

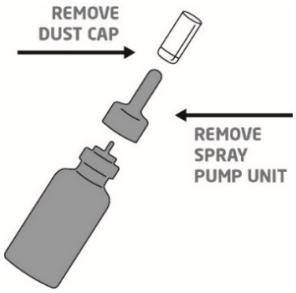
Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

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

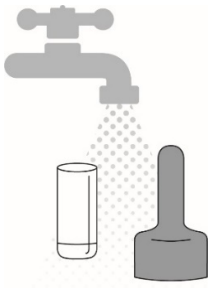
Keep it where young children cannot reach it.

Cleaning instructions

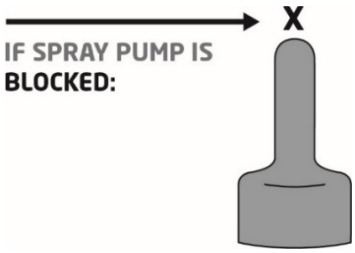
1. Remove the clear dust cap. Gently grip the sides of the white plastic spray tip and pull upwards to lift the plastic spray away from the glass bottle.



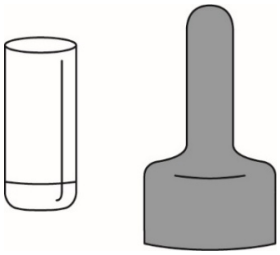
2. Wash the dust cap and plastic spray tip in warm tap water.



3. If plastic spray tip is blocked do not try to unblock MISTY-DUO ALLERGY with a sharp object.
   This can damage the nasal spray and stop you from getting the right dose of MISTY-DUO ALLERGY.



4. Allow to dry completely.



5. When dry, place the clear protective cap onto the plastic spray tip. Then carefully place the spray tip back onto the MISTY-DUO ALLERGY bottle and press down firmly.
6. Re-prime the pump before using MISTY-DUO ALLERGY again.

When to discard your medicine

Discard after 6 months of first opening the bottle.

Do not use this medicine after the expiry date.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Irritated nose. This can cause mild stinging, itching or sneezing • A bitter or unpleasant taste in your mouth • Unpleasant smell • Cough, dry throat or throat irritation • Sore throat • Nose bleeds • Nausea • Headache	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Sleepiness or drowsiness • Feeling weary, exhausted or weak • Damage of the skin and mucous membrane in the nose • Blurred vision or increased pressure in your eye. • 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.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What MISTY-DUO ALLERGY contains

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

Potential allergens	Antimicrobial preservatives: Benzalkonium chloride and phenethyl alcohol

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

What MISTY-DUO ALLERGY looks like

MISTY-DUO ALLERGY (AUST R 415713) is a white suspension.

This medicine comes in an amber coloured glass bottle fitted with a spray pump, applicator and a protective cap. Handle with care.

The 17 mL bottle contains 120 sprays.

MISTY-DUO ALLERGY is available in packs containing 1, 2 or 3 bottles. Not all pack sizes may be marketed.

Who distributes MISTY-DUO ALLERGY

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

Australia

Ph: 1800 288 382

www.tevapharma.com.au

This leaflet was prepared in September 2025.