

AZONAIRE[®] Hayfever & Allergy Prevention & Relief Nasal Spray

mometasone furoate monohydrate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Azonaire Hayfever & Allergy Prevention & Relief. 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. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

WHAT AZONAIRE HAYFEVER & ALLERGY PREVENTION & RELIEF IS USED FOR

Azonaire Hayfever & Allergy Prevention & Relief contains the active ingredient mometasone furoate. This belongs to a family of medicines called corticosteroids, which are used to help reduce inflammation.

Azonaire Hayfever & Allergy Prevention & Relief is sprayed into

the nose to help relieve symptoms that may occur with hayfever or other year-round allergies, including stuffiness (congestion) in the nose, discharge, itching and sneezing.

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.

It may take a few days of use before you feel the full effects of Azonaire Hayfever & Allergy Prevention & Relief. If you suffer from moderate to severe symptoms, you may need to start Azonaire Hayfever & Allergy Prevention & Relief treatment 2-4 weeks before the beginning of the pollen season.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive.

This medicine is available from pharmacists without a prescription.

BEFORE YOU USE AZONAIRE HAYFEVER & ALLERGY PREVENTION & RELIEF

When you must not use it

Do not use the medicine if you have an allergy to:

- any medicine containing mometasone furoate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction 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 use this medicine if:

1. You have a tendency to bleed or recurrent nose bleeding
2. You have severe nose infection, especially fungal infection.
3. You have had recent nose injury or nose surgery; check with your doctor, because you may be told to wait until healing has occurred before using this medicine.

Do not give this medicine to a child under the age of 12 years.

If necessary, your doctor will prescribe a suitable medicine for

children under 12 years of age who have hayfever.

Do not use it after the expiry date (EXP) printed on the pack or if the packaging is torn or shows sign of tampering.

If you are not sure whether you should start taking this medicine, contact your pharmacist or doctor.

Before you start to use it

Tell your pharmacist or doctor if you have or have had any medical conditions, especially the following:

- a history of tuberculosis, or active tuberculosis
- infection of the nose, sinus, mouth, throat, lungs or eye
- sores in the nose
- recent injury or surgery to your nose
- open sores in your nose.

Some symptoms of nasal infection may include:

- fever
- facial pain or swelling
- discoloured nasal discharge.

Tell your pharmacist or doctor if you are taking other corticosteroid medicines, either by mouth, as eye drops, as an asthma inhaler or by injection.

Tell your pharmacist or doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your pharmacist or doctor if you are pregnant or intend to become pregnant.

Your pharmacist or doctor will discuss the possible risks and benefits of using this medicine during pregnancy.

Tell your pharmacist or doctor if you are breastfeeding or plan to breastfeed.

Breastfeeding is not recommended during treatment with this medicine.

If you have not told your pharmacist or doctor about any of the above, tell them before you use this medicine.

Taking other medicines

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

You should tell your doctor who is prescribing a new medication for you that you are using Azonaire Hayfever & Allergy Prevention & Relief.

Some medicines and Azonaire Hayfever & Allergy Prevention & Relief may interfere with each other. These include:

- certain antifungals such as ketoconazole and itraconazole
- some antibiotics such as clarithromycin
- some medicines used to treat HIV infection such as ritonavir and cobicistat-containing products.

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

HOW TO USE AZONAIRE HAYFEVER & ALLERGY PREVENTION & RELIEF

Azonaire Hayfever & Allergy Prevention & Relief is to be sprayed into the nose only.

To prevent symptoms, start using the medicine

- before the hayfever season, or
- before coming into contact with something you know will cause your hayfever.

It may take a few days to get the full effect of this medicine. Therefore, to help reduce the severity of your symptoms, start to use Azonaire Hayfever & Allergy Prevention & Relief for a few days before expected exposure to your usual triggers. If you suffer moderate to severe symptoms, you may need to start treatment 2-4 weeks before the pollen season. It is very important that you use Azonaire Hayfever & Allergy Prevention & Relief regularly. If you stop the treatment when you feel better, your symptoms may return as the medication wears off.

Follow all directions given to you by your pharmacist or doctor carefully and do not use more than the recommended dose.

These directions may differ from the information contained in this leaflet.

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

How much to use

Hayfever and allergies in adults (including the elderly) and children 12 years of age and older:

Two sprays into each nostril once daily.

Do not exceed the maximum dose.

Once your symptoms have improved, reduce the dose to one spray into each nostril once daily.

If symptoms worsen during treatment, see your doctor immediately.

About your nasal spray

Your nasal spray has a dust cap which protects the nozzle and keeps it clean. Remember to take this off before using the spray and to replace it after use.

Do not pierce the nasal applicator.

If you are using the spray for the first time prime the pump by pumping the spray 10 times until a fine mist is produced. If you have not used the

pump for 14 days or more reprime by pumping 2 times.

It is important to clean the nozzle regularly; otherwise, it may not work properly. Remove the dust cap and gently pull off the nozzle. Wash the nozzle and dust cap in warm water and then rinse under a running tap.

Do not try to unblock the nasal applicator by inserting a pin or other sharp object as this will damage the applicator and cause you not to get the right dose of medicine.

Allow the nozzle to dry. Push the nozzle back onto the bottle and replace the dust cap. The pump will need to be reprimed when first used after cleaning.

How to use it

Each pack of this medicine contains an instruction leaflet that tells you the correct way to use it.

1. Shake the bottle gently and remove the dust cap.
2. Gently blow your nose.
3. Close one nostril and put the nozzle into the other nostril.
4. Tilt your head forward slightly, keeping the bottle upright.
5. Start to breathe in gently or slowly through your nose and whilst you are breathing in squirt a spray of fine mist into your nose by pressing down ONCE with your fingers.
6. Breathe out through your mouth. Repeat step 5 to inhale a second spray in the same nostril.
7. Remove the nozzle from this nostril and breathe out through the mouth.
8. Repeat steps 3 to 7 for the other nostril. After using the spray, wipe the nozzle carefully with a clean tissue and replace the dust cap.

How long to use it

See your pharmacist or doctor or if your symptoms are not relieved within 7 days. It generally takes a few days before you notice any improvement in your symptoms.

The medicine only works if it is used on a regular basis.

For the prevention of symptoms relating to seasonal hayfever, Azonaire Hayfever & Allergy Prevention & Relief can be used for up to 6 months.

If you forget to take it

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

Otherwise, use it as soon as you remember, and then go back to use your medicines as you would normally.

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

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

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Azonaire Hayfever & Allergy Prevention and Relief. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

WHILE YOU ARE USING AZONAIRE HAYFEVER & ALLERGY PREVENTION & RELIEF

Things you must do

See your doctor or pharmacist if your symptoms are not relieved within 7 days.

It generally takes a few days before you notice any improvement in your symptoms.

Ask your doctor to examine your nose if you have been using the medicine for several months without a break.

Ask your doctor to examine your nose from time to time to make sure the medicine is working and to prevent unwanted side effects.

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

Tell any other doctors, dentists and pharmacists who are treating you that you are using this medicine.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

See your doctor immediately if you notice the symptoms of severe bacterial infection.

These symptoms may include fever, persistent face/tooth pain on one side of the face, swelling around the eye area, or worsening of symptoms after an initial improvement.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

This medicine generally does not cause any problems with your ability to drive a car or operate machinery.

If you have a lower resistance to infection, avoid coming into contact with anyone who has measles or chickenpox especially while you are using cortisone-type medicines. Tell your doctor if you do.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using this medicine.

The doctor will decide whether any change in your treatment is needed.

This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age, you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Most people do not have any problems after using the nasal spray. However, a few people may find that they suffer from one or more of the following:

- headache
- sneezing
- nosebleeds or blood-tinged mucus
- glaucoma
- increased intraocular pressure
- cataracts
- blurred vision
- eye pain or visual disturbances

- sore throat or burning or irritation inside the nose after using this medicine. These symptoms are consistent with the use of corticosteroid nasal sprays.

If you develop a rash, wheezing or breathlessness, stop using the nasal spray, as you may be allergic to it and contact your doctor immediately.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

AFTER USING AZONAIRE HAYFEVER & ALLERGY PREVENTION & RELIEF

Storage

Keep the nasal spray in a cool dry place where the temperature stays below 25°C. Do not freeze. Store it away from heat.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

Discard 2 months after opening.

Further information

Drug testing for sports events:

This product is a corticosteroid for intranasal administration; it is not a restricted drug for sports.

Corticosteroid may be detected in blood and in the urine during drug testing; thus prior written permission for its use may be required by some sport agencies.

PRODUCT DESCRIPTION

What it looks like

The nasal spray is a white to off-white suspension contained in a plastic bottle with a metered-dose, manual spray pump for intranasal administration.

Ingredients

Active ingredient:

Mometasone furoate monohydrate.

Inactive ingredients:

Microcrystalline cellulose and carmellose sodium glycerol, citric acid monohydrate, sodium citrate dihydrate, polysorbate 80, water for injections.

Preservatives:

Benzalkonium chloride

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

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This leaflet was prepared in March
2023.

Australian Registration Numbers:

60 metered doses per pack

140 metered doses per pack

AUST R 228266