

## BAYER ARTWORK PANEL



Bayer Ref No: **BAY497185**  
Trident Reference No: TR2320062  
Brand: Clarinaze  
Range: N/A  
Product: 0.05% Spray  
Pack Type: Leaflet  
Pack Size: 140 dose  
Action: **C**  
Date: 16/11/21  
Country: UK

Finished Goods Code: **84665843**  
Synaps Request Code: **TL027199**  
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## ARTWORK APPROVAL PANEL

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Package leaflet: Information for the user

# Clarinaze®

Allergy Control 0.05% nasal spray  
mometasone furoate

**Please read this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine is available without prescription, but you still need to use Clarinaze Allergy Control carefully to get the best results from it.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your pharmacist or doctor if you do not feel better or if you feel worse after 14 days**

### What is in this leaflet

- What Clarinaze Allergy Control is and what it is used for
- What you need to know before you use Clarinaze Allergy Control
- How to use Clarinaze Allergy Control
- Possible side effects
- How to store Clarinaze Allergy Control
- Contents of the pack and other information

## 1. What Clarinaze Allergy Control is and what it is used for

### What is Clarinaze Allergy Control?

Clarinaze Allergy Control nasal spray contains mometasone furoate, one of a group of medicines called corticosteroids. When mometasone furoate is sprayed into the nose, it can help to relieve inflammation (swelling and irritation of the nose), sneezing, itching and a blocked up or runny nose.

### What is Clarinaze Allergy Control used for?

Clarinaze Allergy Control is used to treat the nasal symptoms of hayfever (also called seasonal allergic rhinitis) and perennial allergic rhinitis in adults aged 18 years and older.

Hayfever, which occurs at certain times of the year, is an allergic reaction caused by breathing in pollen from trees, grasses, weeds and also moulds and fungal spores. Perennial allergic rhinitis occurs throughout the year and symptoms can be caused by a sensitivity to a variety of things including house dust mite, animal hair (or dander), feathers and certain foods. Clarinaze Allergy Control reduces the swelling and irritation in your nose thereby relieving sneezing, itching and a blocked-up or runny nose caused by hayfever or perennial allergic rhinitis.

## 2. What you need to know before you use Clarinaze Allergy Control

### Do not use Clarinaze Allergy Control

- if you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of this medicine (listed in section 6).
- if you have an untreated infection in your nose. Use of Clarinaze Allergy Control during an untreated infection in your nose, such as herpes, can worsen the infection. You should wait until the infection is resolved before you start using the nasal spray.
- if you have recently had an operation on your nose or you have injured your nose. You should not use the nasal spray until your nose has healed.
- if you are under 18 years of age.
- if you are pregnant or breastfeeding without talking to your doctor first.
- for more than 3 months without consulting your doctor.

### Warnings and precautions

Talk to your doctor or pharmacist before using Clarinaze Allergy Control

- if you have or have ever had tuberculosis.
- if you have any other infection.
- if you are taking other corticosteroid medicines, either by mouth or by injection.
- if you have cystic fibrosis.

While you are using Clarinaze Allergy Control, talk to your doctor or pharmacist

- if your immune system is not functioning well (you have difficulty fighting infection) and you come into contact with anyone with measles or chickenpox. You should avoid coming into contact with anyone who has these infections.
- if you have an infection of the nose or throat.
- if you have persistent irritation to the nose or throat.
- if you experience blurred vision or other visual disturbances.

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body.

### Other medicines and Clarinaze Allergy Control

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines whilst using Clarinaze Allergy Control, including medicines obtained without a prescription.

Some medicines may increase the effects of Clarinaze Allergy Control and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Talk to your pharmacist before using this medicine if you are taking any prescribed corticosteroid medicines (including eczema creams, asthma inhalers, injections, nasal sprays and eye or nose drops). A few people may find that once they discontinue oral or injected corticosteroids they suffer from some undesirable effects, such as joint or muscular pain, weakness and depression. You may also seem to develop other allergies, such as itchy, watering eyes or patches of red and itchy skin. If you develop any of these effects, you should contact your doctor or pharmacist.

### Pregnancy and breast-feeding

Talk to your doctor or pharmacist before using Clarinaze Allergy Control if you are pregnant, trying to become pregnant or are breast-feeding.

### Driving and using machines

There is no known information on the effect of Clarinaze Allergy Control on the ability to drive or use machinery.

### Clarinaze Allergy Control contains benzalkonium chloride

Clarinaze Allergy Control contains 0.02mg benzalkonium chloride per spray which is equivalent to 0.2mg/g. This ingredient may cause irritation or swelling inside the nose, especially if used for a long time.

## 3. How to use Clarinaze Allergy Control

Always use Clarinaze Allergy Control according to the instructions in this leaflet. You should check with your doctor or pharmacist if you are not sure. Do not use a larger dose or use the spray more often or for longer than instructed.

### Treatment of Symptoms of Hayfever and Perennial Allergic Rhinitis Adults (aged 18 years and over)

**The usual dose is two sprays into each nostril once a day.**

- Once your nasal symptoms are under control, you may reduce the dose to one spray into each nostril once a day.
- Use the lowest possible dose to control your symptoms.
- Do not use more than four sprays in a day.
- Do not use more than the recommended dose.

If your symptoms have not improved within 14 days, you should see your doctor or pharmacist.

In some patients Clarinaze Allergy Control begins to relieve nasal symptoms within 12 hours after the first dose; however full benefit of treatment may not be seen in the first two days. Therefore, you should continue regular use to achieve the full benefit of treatment.

If you suffer badly from hayfever, you can start using Clarinaze Allergy Control some days before the start of the pollen season, as this will help to prevent your hayfever symptoms from occurring.

### Children or adolescents under 18 years

Do not use in children and adolescents under 18 years.

### Preparing your nasal spray for use

Your Clarinaze Allergy Control 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.

If you are using the spray for the first time you need to "prime" the bottle by pumping the spray 10 times until a fine mist is produced:

- Gently shake the bottle.
- Put your forefinger and middle finger either side of the nozzle and your thumb underneath the bottle. **Do Not** pierce the nasal applicator.
- Point the nozzle away from you and then press down with your fingers to pump the spray 10 times until a fine mist is produced.

If you have not used the spray for 14 days or more, you need to "re-prime" the bottle by pumping the spray 2 times until a fine mist is produced.

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
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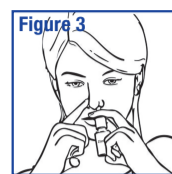
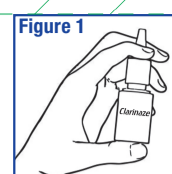
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### How to use your nasal spray

1. Shake the bottle gently and remove the dust cap. (Figure 1)
2. Gently blow your nose.
3. Close one nostril and put the nozzle into the other nostril as shown. (Figure 2) Tilt your head forward slightly, keeping the bottle upright.
4. 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.
5. Breathe out through your mouth. Repeat step 4 to inhale a second spray in the same nostril if applicable.
6. Remove the nozzle from this nostril and breathe out through the mouth.
7. Repeat steps 3 to 6 for the other nostril (Figure 3).



After using the spray, wipe the nozzle carefully with a clean handkerchief or tissue and replace the dust cap.

#### Cleaning your nasal spray

- It is important to clean your nasal spray 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 dust cap and nozzle to dry in a warm place.
- Push the nozzle back onto the bottle and replace the dust cap.
- The spray will need to be primed again with 2 sprays when first used after cleaning.

#### If you use more Clarinaze Allergy Control than you should

Tell your doctor or pharmacist if you accidentally use more than this leaflet recommends.

If you use steroids for a long time or in large amounts they may, rarely, affect some of your hormones.

#### If you forget to use Clarinaze Allergy Control

If you forget to use your nasal spray at the right time, use it as soon as you remember, then carry on as before. Do not take a double dose to make up for a forgotten dose.

#### If you stop using Clarinaze Allergy Control

In some patients Clarinaze Allergy Control should begin to relieve symptoms 12 hours after the first dose; however full benefit of treatment may not be seen for up to two days. It is very important that you use your nasal spray regularly. If you stop treatment before the end of the allergy season your symptoms may reoccur.

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

## 4. Possible side effects

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

Immediate hypersensitivity (allergic) reactions may occur after use of this product. These reactions may be severe. You should **stop taking** Clarinaze Allergy Control and get **immediate medical help** if you experience symptoms such as:

- swollen face, tongue or pharynx
- trouble swallowing
- hives
- wheezing or trouble breathing

**Stop taking** the medicine and **tell your doctor** if you experience:

- eye problems such as pain or blurred vision.
- nasal problems such as pain and/or persistent bleeding.

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body. The following side effects may occur:

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

- headache
- sneezing
- nose bleeds [occurred very commonly (may affect more than 1 in 10 people) in people with nasal polyps receiving two sprays in each nostril twice a day]
- sore nose or throat
- ulcers in the nose
- respiratory tract infection

#### Not known (frequency cannot be estimated from the available data):

- increase in pressure in the eye (glaucoma) and/or cataracts causing visual disturbances
- damage to the partition in the nose which separates the nostrils
- changes in taste and smell
- difficulty in breathing and/or wheezing
- blurred vision

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Clarinaze Allergy Control

- Do not store the nasal spray above 25°C. Do not freeze it.
- The bottle should be used within 2 months of first opening.
- 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 and carton after EXP. The expiry date refers to the last day of that month.

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 Clarinaze Allergy Control contains

- The active substance is mometasone furoate. Each spray contains 50 micrograms of mometasone furoate, as the monohydrate.
- The other ingredients are dispersible cellulose, glycerol, sodium citrate, citric acid monohydrate, polysorbate 80, benzalkonium chloride, purified water.

#### What Clarinaze Allergy Control looks like and contents of the pack

Clarinaze Allergy Control is a nasal spray suspension.

Each 10g bottle contains 60 sprays, each 18g bottle contains 140 sprays. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is:  
Bayer plc,  
400 South Oak Way,  
Reading, RG2 6AD, UK

The manufacturer is:  
Schering-Plough Labo NV,  
Heist-op-den Berg, Belgium

This leaflet was last revised in November 2021.

Bayer

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