

## **Package leaflet: Information for the user**

### **MUZANLO 50 micrograms/actuation Nasal Spray, Suspension**

Mometasone furoate

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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 doctor if you do not feel better or if you feel worse after 14 days.

#### **What is in this leaflet**

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

#### **1. What MUZANLO is and what it is used for**

##### **What is MUZANLO?**

MUZANLO 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 MUZANLO used for?**

MUZANLO is used to treat the 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 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. MUZANLO reduces the swelling and irritation in your nose and thereby relieving sneezing, itching and a blocked-up or runny nose caused by hayfever or perennial rhinitis.

#### **2. What you need to know before you use MUZANLO**

##### **Do not use MUZANLO**

- 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 MUZANLO 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 MUZANLO

- 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 MUZANLO, talk to your doctor

- if your immune system is not functioning well (if you have difficulty in 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 MUZANLO**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines whilst using Muzanlo, including medicines obtained without a prescription.

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.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

### **Driving and using machines**

There is no known information on the effect of MUZANLO on the ability to drive or use machinery

### **MUZANLO contains benzalkonium chloride**

MUZANLO contains benzalkonium chloride which may cause nasal irritation or swelling inside the nose, especially if used for a long time.

### 3. How to use MUZANLO

Always use this medicine exactly as described in this leaflet. 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 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 MUZANLO begins to relieve 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 MUZANLO some days before the start of the pollen season, as this will help to prevent your hayfever symptoms from occurring.

##### **Children and adolescents under 18 years**

Do not use in children and adolescents under 18 years

##### **Preparing your nasal spray for use**

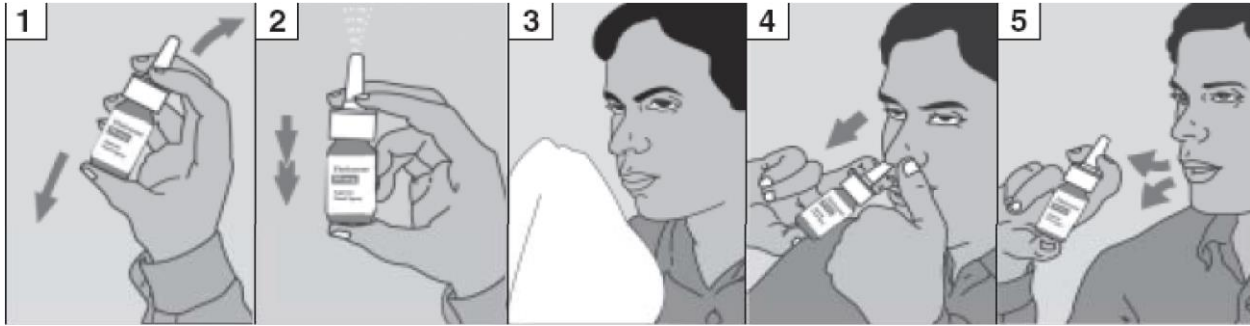
If you are using the spray for the first time, you should prime the pump by pumping the spray 10 times until a fine mist is produced. To do this:

1. Gently shake the bottle and remove the dust cap.
2. Put your forefinger and middle finger on the collar either side of the nozzle and your thumb underneath the bottle.
3. Keep the thumb still and press down with your fingers to pump the spray, holding the nozzle away from you. Pump the spray 10 times until a fine mist is produced.

If you have not used the spray for 14 days or longer, you should re-prime the pump by pumping the spray 2 times until a fine mist is produced.

If there is no spray and you think the nozzle may be blocked, clean it. (Refer to cleaning instructions below). **DO NOT** try to unblock the spray hole with a pin or other sharp object as this will destroy the spray mechanism.

## How to use your nasal spray



1. Shake the bottle gently. (Figure 1)
2. Remove the dust cap. (Figure 2)
3. Blow your nose gently. (Figure 3)
4. Hold the bottle as shown. Place your finger on your nose to close one nostril, and put the nozzle in your other nostril. Tilt your head forward and keep the bottle upright. Start to breathe in slowly through your nose and at the same time press down firmly on the collar of the bottle with your finger, which releases a spray of mometasone furoate. (Figure 4)
5. Breathe out through your mouth. Repeat step 4 if more than one spray is required into the same nostril. Remove the nozzle from the nostril and breathe out through your mouth. (Figure 5)

Repeat steps 4 to 5 for the other nostril. (Figure 4 and 5)

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

### Cleaning your nasal spray

1. Clean your nasal spray at least once a week as it can become blocked, stopping it from working properly.
2. Remove the dust cap.
3. Gently pull upwards on the white collar to remove the nozzle.
4. Soak the nozzle and dust cap in warm water for a few minutes, and then rinse under a running tap.
5. Allow to dry in a warm place before putting back together. Do not dry near a very hot place.
6. Re-fit the nozzle and 'prime' the bottle if necessary by pumping the spray a few times to produce a fine mist.
7. 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.

### If you use more MUZANLO 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 MUZANLO

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 use a double dose to make up for a forgotten dose.

### **If you stop using MUZANLO**

In some patients MUZANLO 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 before end of the allergy season your symptoms may reoccur.

If you have any further questions on the use of this medicine, 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 medicine. These reactions may be severe. You should **stop using** MUZANLO and get **immediate medical help** if you experience symptoms such as:

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

**Stop using** 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 at: [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 MUZANLO**

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

- The active substance is mometasone furoate. Each spray (actuation) contains 50 micrograms of mometasone furoate (as monohydrate) as delivered dose (ex actuator).
- The other ingredients are microcrystalline cellulose and carmellose sodium, glycerol, sodium citrate, citric acid monohydrate, polysorbate 80, benzalkonium chloride, water for injection.

### **What MUZANLO looks like and contents of the pack**

MUZANLO is white to off-white coloured homogeneous re-dispersible suspension.

MUZANLO is packed in white opaque high density polyethylene bottle, fitted with a white-metered atomising pump, white nasal adaptor and a translucent dust cap for nozzle.

Pack size: 18g bottle (140 spray)

### **Marketing Authorisation Holder and Manufacturer**

Cipla (EU) Limited  
Dixcart House, Addlestone Road  
Bourne Business Park, Addlestone,  
Surrey, KT15 2LE,  
United Kingdom

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