

## Patient Information Leaflet

### MOMEX®

#### Mometasone furoate 50 micrograms per actuation, nasal spray

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you. If you have questions or you notice side effects not mentioned in this leaflet, contact your doctor or your healthcare professional. Do not pass this medicine on to others.**

#### 1. What Momex is and what it is used for

Momex nasal spray contains mometasone furoate, one of a group of medicines called corticosteroids (ATC- R01AD09).

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.

Momex is used to treat the symptoms of seasonal allergic rhinitis (hay fever) and perennial (long lasting) rhinitis in adults and children aged 3 and older.

Momex is used to treat nasal polyps in adults aged 18 and over.

#### 2. What you need to know before you use Momex

##### Do not use Momex if

- you are allergic (hypersensitive) to mometasone furoate or to any other ingredient of this medicine listed in section 6.
- you have an untreated infection in your nose. Use of Momex 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.
- 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.

##### Warnings and precautions

Talk to your doctor before using Momex if

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

While using Momex, talk to your doctor, if

- your immune system is not functioning well (you have a higher risk of being infected compared to other healthy individuals, for example: you should avoid coming into contact with anyone who has chickenpox or measles);
- you have an infection or persistent irritation of the nose or throat.
- you are using this medicine for several months or longer.

If your eyes are itching or irritated, or if you have glaucoma and/ or cataract: your doctor may recommend that you use other treatments with Momex;

If you are using the medicine for several months or longer, side effects may occur due to the medicine being absorbed in the body.

### **Children**

The use of high doses for long periods of time may cause certain side-effects, such as slowed growth rate in children; therefore, it is recommended that the height of children is regularly monitored.

### **Other medicines and Momex**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines without a prescription.

If you are taking other corticosteroid medicines for allergy, either by mouth or injection, your doctor may advise you to stop taking them once you begin using Momex.

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

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

If you think you might be pregnant, or are planning to get pregnant or if you are breast-feeding, you must tell your doctor that you are taking medicines.

There is little or no information on the use of mometasone furoate nasal spray in pregnant women. It is not known if mometasone furoate is found in breast milk. Corticosteroids are generally excreted into breast milk. Therefore, caution should be taken when using this medicine in breast-feeding women.

### **Driving and using machines**

Momex does not have a known effect on the ability to drive and use machines.

### **Important information about some ingredients of Momex**

Momex contains 0.02 mg of benzalkonium chloride per actuation (spray). It may cause irritation or swelling inside the nose, especially if used for a long time.

### **3. How to use Momex**

Always use Momex exactly as your doctor or health care provider has told you.

Do not use this medicine for a longer period of time than your doctor has prescribed for you.

#### **Seasonal hay fever and perennial rhinitis**

**Adults and adolescents:** the recommended dose is two sprays in each nostril once a day. Once symptoms are controlled, dose reduction to one spray in each nostril may be effective for maintenance.

If you do not start to feel any better, you should see your doctor and he/she may tell you to increase the dose; the maximum daily dose is four sprays into each nostril once a day. Dose reduction is recommended following control of symptoms.

**Children 3 to 11 years:** the usual dose is one spray into each nostril once daily.

If you or your child suffer badly from seasonal hay fever, your doctor may tell you to start using Momex some days before the start of the allergy season, as this will help to prevent your hay fever symptoms from occurring.

Prophylaxis must be initiated up to 2-4 weeks prior to the anticipated start of the allergy season. Benefit of treatment may be achieved in the first two days. Maximum benefit is achieved within 1-2 weeks following initiation of treatment. Therefore, patients should continue regular use to achieve full therapeutic benefit. For patients who use Momex at regular intervals for treatment of hay fever, recommended dose is a spray into each nostril once a day.

#### **Nasal Polyposis in adults, elderly, patients aged 18 years and older**

The recommended starting dose is two sprays in each nostril once daily. If symptoms are inadequately controlled 5 to 6 weeks after the initiation of treatment, the dose may be increased to a daily dose of two sprays in each nostril twice daily. The dose should be determined according to the lowest dose at which effective control of symptoms is maintained. If no improvement in symptoms is seen after 5 to 6 weeks of twice daily administration, you should contact your doctor.

**Instructions for proper use of MOMEX for intranasal use. Please read the following instructions carefully before use.**

1. Gently shake the bottle before each use;

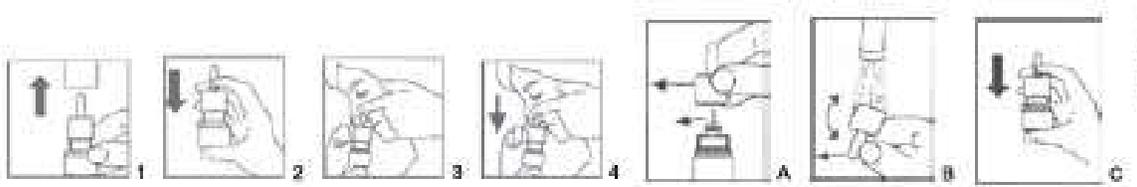
2. Remove the plastic cap (fig.1).

If you are using your medicine for the first time, support the bottle from bottom with your thumb. Place your index finger and middle finger on the white applicator and spray the medicine by pressing down. Repeat this procedure by pumping the spray 10 times or until a fine mist is produced (fig.2). Your medicine is ready for use. Even if you have not used your medicine for a week, you do not need to readjust. However, if you have not used your medicine for more than one week, you need to pump the spray 2 to 3 times until a fine mist is produced.

3. Gently blow your nose to discharge your nostrils or exhale through your nose.
4. Close one nostril and put the end of the applicator into the other nostril (fig.3).
5. Tilt your head forward slightly, keeping the bottle upright. Start to breathe in slowly through your nose and whilst you are breathing in, squirt a spray of medicine into your nose by pressing down once on the white applicator with your fingers (fig.4). Do not apply on the wall between two nostrils.
6. After the procedure, remove the bottle from this nostril and breathe out through the mouth.
7. Repeat the exact procedure with your other nostril.
8. Wipe the nasal applicator carefully with a clean handkerchief or tissue and replace the plastic cap.

### Cleaning the Nasal Spray

It is important to clean your nasal applicator regularly. Otherwise it may not spray properly. Remove the plastic cap and rinse with clean tap water (fig.A). Slowly pull the nasal applicator up. Rinse the nasal applicator with clean tap water (fig.B). Do not poke the hole with drilling material or needle. Replace the nasal applicator in a way that it is seated onto the pump stem. Support the bottle from the bottom with your thumb (fig.C). Place your index finger and middle finger on the white applicator and spray the medicine by pressing down. Repeat this procedure until a fine mist is produced. Replace the plastic cap you have cleaned again with tap water.



Discard the bottle of nasal spray 2 months after first use.

**If you use more Momex than you should** (more than your daily dose)

contact your doctor.

**If you forget to use Momex**

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

**If you stop using Momex**

Your doctor will advise you how long you should use this medicine.

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

**4. Possible side effects**

Like all medicines, Momex 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 using Momex and get immediate medical help if you experience symptoms such as: swollen face, tongue or pharynx; trouble swallowing; hives; wheezing or trouble breathing.

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

**Other side effects:** Most people do not have any problems after using the nasal spray. However, some people, after using Momex or other corticosteroid nasal sprays, may find that they suffer from

***Common side effects (up to 1 in 10 people):***

- headache;
- sneezing;
- nose bleeds (occurred very commonly (more than 1 in 10 people) in people with nasal polyps receiving two sprays of mometasone furoate in each nostril twice a day);
- sore nose or throat;
- ulcers in the nose;
- respiratory tract infection.

***Not known frequency: 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
- hypersensitivity reactions (see above)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or health care provider.

## **5. How to store Momex**

Keep out of the reach and sight of children.

Store below 30°C. Do not freeze.

Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

The bottle should be used within 2 months of first opening.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. Contents of the pack and further information**

### **What Momex contains**

The active substance is mometasone furoate monohydrate equivalent to 50 micrograms mometasone furoate per spray (actuation).

The other ingredients are microcrystalline cellulose, carmellose sodium, glycerol, citric acid monohydrate, sodium citrate, polysorbate 80, benzalkonium chloride (0.02mg /spray), purified water.

### **What Momex looks like and content of the pack**

White, opaque suspension in a polyethylene bottle with spray nozzle delivering 140 sprays.

Box with one spray-bottle and a leaflet.

**Momex is a prescription medicine.**

### **Manufacturer**

Deva Holding A.Ş. Çerkezköy Organize Sanayi Bölgesi , Karaağaç Mah., Atatürk Cad. No:  
32 – Kapaklı, Tekirdağ, Turkey.

**Marketing Authorisation Holder**

Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.

**Date of revision of the leaflet**

05/2024