

Patient Information Leaflet

MOMEX®

NASAL SPRAY, SUSPENSION

Mometasone Furoate 50 micrograms per actuation

Read all of 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. **If you have any further questions, ask your doctor or pharmacist.**

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- 1. What is Momex® and what it is used for:** (ATC code: R01AD09) Momex® 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. Momex® is used: **1.** to treat the symptoms of seasonal allergic rhinitis (also called hayfever) and perennial (long lasting) rhinitis in adults and children aged 3 and older; 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 any of the other ingredients of this medicine (listed in section 6); if 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; 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. **Warnings and precautions. Talk to your doctor before using Momex®:** if you have or have ever had tuberculosis; if you have any other untreated infections; if you are taking other corticosteroid medicines, either by mouth or by injection, if you have cystic fibrosis. **While you are 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); if you have an infection or persistent irritation to the nose or throat; 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 drug being absorbed in the body; in 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; Momex® contains benzalkonium chloride, which may cause nasal irritation. **Other medicines and Momex®:** No known interaction. **Pregnancy, breast-feeding and fertility:** There is little or no information on the use of Momex® in pregnant women. It is not known if mometasone furoate is found in breast milk. 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 taking this medicine. Corticosteroids are generally excreted into breast milk. Therefore, caution should be taken for its use in breast-feeding women. **Driving and using machines:** Momex® does not have a known effect on the ability to drive and use machines.
- 3. How to use Momex®:** **Always use it exactly in the dose your doctor or pharmacist has told you.** Do not use it for a longer period of time than your doctor has prescribed for you.

Seasonal allergic rhinitis and perennial rhinitis: for 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 or 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. For children aged 3 to 11 years the usual dose is one spray into each nostril once daily. If you or your child suffer badly from seasonal allergic rhinitis, 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 allergic rhinitis 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 allergic rhinitis, recommended dose is a spray into each nostril once a day. For children between the ages of 2 and 11 years the usual recommended dose is one spray in each nostril once a day.

Nasal Polyposis: in adults, geriatric patients and 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: MOMEX® has been developed for intranasal use. Please read the following instructions carefully before use.

1. Gently shake the bottle before each use.
2. Remove the plastic cap.

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. 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.

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. *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. Slowly pull the nasal applicator up. Rinse the nasal applicator with clean tap water. Do not poke the hole with drilling material or needle. Re-place the nasal applicator in a way that it is seated onto the pump stem. Support the bottle from the 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 until a fine mist is produced. Replace the plastic cap you have cleaned again with tap water.

If you accidentally used more Momex® than you should (more than your usual daily dose) then contact your doctor. **If you forget to use Momex®,** just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

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 taking 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 drug being absorbed in the body. 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 Momex® two sprays in each nostril twice a day); sore nose or throat; ulcers in the nose; respiratory tract infection. Not known frequency: 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. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
5. **How to store Momex®:** Store below 30 °C. Do not freeze. Keep out of reach and sight of children. 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.
6. **Momex® contains per actuation:** As active substance: mometasone furoate monohydrate equivalent to 50 micrograms mometasone furoate. Other ingredients: sodium citrate, benzalkonium chloride 0.02 mg, glycerol, microcrystalline cellulose, carmellose sodium, citric acid monohydrate, polysorbate 80, purified water. **Momex® is presented** as a nasal spray, white-colour, homogenous suspension, when shaken. Packages: polyethylene bottle with spray nozzle containing 18 g suspension, containing suspension for 140 actuations. **Momex®** is a prescription only medicine.
7. **Name of Manufacturer:** DEVA HOLDING A.Ş. Çerkezköy Organize Sanayi Bölgesi, Karaağaç Mah, Atatürk Cad., No: 32 Kapaklı-Tekirdağ, Turkey
8. **Registration/Licence Holder:** Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.
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