

PATIENT INFORMATION LEAFLET

MOMETIX AQ 0.005 % NASAL SPRAY, Suspension

Nasal suspension used with metered spray pump.

Active pharmaceutical ingredient: Each spray contains 51.75 micrograms of mometasone furoate monohydrate equivalent to 50.00 micrograms of mometasone furoate.

Excipients: Microcrystalline cellulose, sodium carboxymethylcellulose, glycerin, citric acid monohydrate, sodium citrate dihydrate, polysorbate 80, benzalkonium chloride and purified water.

Read all of this LEAFLET carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed personally for you. Do not pass it on to others.
- If you go to the doctor or hospital during the use of this medicine, tell your doctor that you are taking it.
- Follow the instructions in these instructions. Do not use high or low doses other than the recommended dose.

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Titles are included.

1. WHAT MOMETIX IS AND WHAT IT IS USED FOR

What is MOMETIX and used for ?

MOMETIX AQ Nasal Spray contains mometasone furoate, which belongs to a group of drugs called corticosteroids. Mometasone furoate should not be confused with anabolic steroids which are misused by some athletes and taken by tablets or injections. When small amounts of mometasone furoate are sprayed into the nose, it helps relieve inflammation, itching, congestion and sneezing in the nose.

MOMETIX AQ is used in the treatment of hay fever (also known as seasonal allergic rhinitis) and year-round rhinitis (nasal inflammation) in children and adults aged 6 years and older.

MOMETIX AQ is indicated for the prophylaxis of seasonal allergic rhinitis in adults and adolescents 12 years and older.

MOMETIX AQ can be used in children aged 2-6 years with a diagnosis of allergic rhinitis.

Prophylactic treatment should be started 2-4 weeks before the expected onset of the pollen season.

MOMETIX AQ is also used in the treatment of nasal polyps (benign neoplasm) in adults 18 years and older.

What is hay fever and year-round rhinitis?

Hay fever during certain periods of the year is an allergic reaction caused by inhalation of wood, grass, grass pollen, as well as mold and fungal spores.

Year-round rhinitis can be caused by susceptibility to a variety of substances, including house dust mites, animal dandruff, feather and certain foods. These allergies cause runny nose and sneezing and cause nasal congestion due to swelling in the nasal mucosa. MOMETIX AQ reduces swelling and irritation in the nose, thereby relieving sneezing, nasal itching, discharge and congestion.

What are nasal polyps?

Nasal polyps are small formations on the nasal mucosa and are usually seen in both nostrils. The main symptom is a sense of congestion in the nose and may affect breathing through the nose. Nasal discharge and loss of taste and smell sensation may also be seen. MOMETIX AQ reduces inflammation in the nose and allows the polyps to shrink gradually.

Things need to be consider before you use MOMETIX

Do not use MOMETIX in the following situations

If:

- you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of MOMETIX.
- you have an infection in your nose. 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.

Use MOMETIX carefully in the following situations

If:

- you have or have ever had tuberculosis.
- you have herpes simplex (virus) infection in the eye
- you have any other type of infection.
- you are taking other corticosteroid medicines, either by mouth or by injection.
- you have cystic fibrosis.

While using MOMETIX, avoid coming into contact with anyone who has measles or chickenpox. You should tell your doctor if you do come into contact with anyone who has these infections.

Please consult your doctor if these warnings apply to you, even at any time in the past.

Using MOMETIX AQ with food and drink:

MOMETIX can be used with or without food.

Pregnancy

Consult your doctor or pharmacist before taking this medicine,

You should not use MOMETIX if you are pregnant or planning to have a baby unless your doctor has told you to.

As with other nasal corticosteroid preparations, a decision to whether use MOMETIX or not must be made by taking into account the benefits of the therapy to any potential risks to the mother and foetus.

Tell your doctor immediately if you notice that you are pregnant while you are using this medicine.

Lactation

Consult your doctor or pharmacist for advice before taking this medicine,

If you are breast-feeding or thinking about to breast-feed, ask your doctor or pharmacist for advice before taking MOMETIX. As with other nasal corticosteroid preparations, a decision must be made whether to discontinue breast-feeding or to discontinue/abstain from MOMETIX therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Driving and using machines

There is no known information on the effect of MOMETIX AQ on the ability to drive or use machinery.

Important information on some inactive ingredients of MOMETIX

MOMETIX contains benzalkonium chloride which may cause nasal irritation.

Using other medicines

Tell your doctor about all medicines you use, including prescription and over-the-counter medications and herbal supplements. Some drugs can effect on the mechanism of action of MOMETIX or MOMETIX can effect on the mechanism of action of some drugs.

If you are taking corticosteroid medications for allergies by oral route or by injection, your doctor may advise you to stop taking them before you begin using MOMETIX AQ . Some people may experience some undesirable effects such as muscle or joint pain, weakness and depression when they stop oral or injection corticosteroids. If you experience these events, tell your doctor; your doctor will advise you whether to continue using the nasal spray. You may also experience other allergies such as itching in the eyes, watering or itching or redness of the skin. If you experience any of these effects and are worried, you should consult your doctor.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other prescribed or non-prescribed medicines.

3. HOW TO USE MOMETIX?

Always use MOMETIX exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Do not use a higher dose or do not use the spray more often or for longer than your doctor tells you to.

Instructions for proper use and frequency of dosage / administration:

- Hay fever and Perennial Rhinitis:

Use in adults and children over 12 years old:

The usual dose is two sprays into each nostril once a day in adults (include elderly people) and children over 12 years old.

Once your symptoms are under control, your doctor may advise you one spray into each nostril once a day.

If you do not start to feel any better, you should see your doctor. He or she may tell you to increase the dose to four sprays into each nostril once a day. After your symptoms are under control, your doctor advise you to decrease the dose to two sprays into each nostril once a day.

Use in children aged 2 to 11 years:

The usual dose is one spray into each nostril once daily.

Long term use of nasal steroids at high doses may cause slowing of growth in children. Your doctor may check your child's height at intervals during treatment and reduce the dose if any effects are seen.

If your hay fever symptoms get worse, your doctor may tell you to start using MOMETIX AQ two to four weeks before the start of the pollen season, as this will help to prevent your hay fever symptoms from occurring. Your doctor may recommend that you use other treatments with MOMETIX AQ, particularly if your eyes are itching or irritated. At the end of the pollen season your hay fever symptoms may heal and then you don't need to treatment.

- Nasal Polyps

The usual starting dose of adults aged 18 and over is two sprays into each nostril once daily.

If symptoms are not controlled after 5 to 6 weeks, the dose may be increased to two sprays in each nostril twice daily. Once symptoms are under control, your doctor may advise you to decrease your dose.

If no improvement in symptoms is seen after 5 to 6 weeks of twice daily administration, you should contact your doctor to discuss other treatments to replace MOMETIX AQ.

Method of administration:

Preparing your nasal spray for use:

Your Mometix AQ Nasal Spray has a dust cap which protects the nozzle and keeps it clean. Take this off before using the spray and to replace it after use.

Do not pierce the nasal applicator.



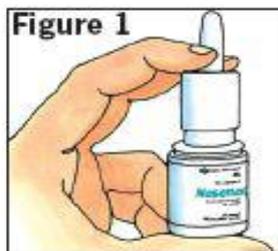
On first use, to adjust the spray pump, the drug should be sprayed, usually 10 times, until it appears that it is spraying properly:

1. Shake well the bottle before each use.
2. Place the forefinger and the middle finger on both sides of the nose and your thumb under the bottle
3. Point the nozzle away from your nostril and then press down with your fingers to pump the spray.

If the spray pump has not been used for 14 days or more, the spray should usually be sprayed 2 times before use to adjust the spray pump until it appears that it has sprayed properly.

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 breathing slowly through your nose and press ONCE with your fingers as you breathe in.
5. Breathe out of your mouth. Repeat step 4 to the same nostril once more.
6. Remove the nozzle from this nostril and breathe out of your mouth.
7. Repeat steps 3 to 6 for the other nostril. After using the spray, wipe the nozzle with a clean tissue or handkerchief and close the cap. (Figure 3).



Cleaning your nasal spray

It is important to clean your nasal spray regularly, otherwise it may not work properly. Remove the dust cap and pull off the nozzle. Wash the nozzle and dust cap in hot water and then dry. Do not attempt to puncture the tip of the spray pump with a needle or other sharp object; because this will damage the pump and prevent you from taking the correct dose of medication. Allow the dust cap and nozzle to dry in a hot place. Push the nozzle back onto the bottle and replace the dust cap. The spray will need to be adjusted again with 2 sprays when first used after cleaning.

Using in other ages:

In children: Adults should help to children while they used this medicine.

In elderly: No special using needed.

Special use cases:

Renal/hepatic failure: There is no data for patients with renal/hepatic failure.

If you have an impression that the effect of MOMETIX AQ is too strong or weak, talk to your doctor or pharmacist.

If you use more MOMETIX AQ than you should

Tell a doctor or a pharmacist if you took MOMETIX AQ more than you should.

If you use steroids for a long time or in large amounts they may rarely affect some of your hormones. In children this may affect growth and development.

If you forget to use MOMETIX

Try to take your medicine as recommended.

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.

Effects that may occur when treatment with MOMETIX AQ is terminated

In some patients MOMETIX AQ 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. Do not stop your treatment even if you feel better unless your doctor told you to do.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, there may be side effects in people who are sensitive to substances contained in MOMETIX AQ.

Stop using MOMETIX AQ and notify your doctor IMMEDIATELY or contact the emergency department of your nearest hospital if any of the following occurs:

Sudden hypersensitivity reaction (such as bronchospasm (spasm in the bronchi), dyspnea) may occur after intranasal (intranasal) administration.

Very rare: Anaphylaxis (hypersensitivity reaction) and angioedema (itchy skin condition) have been reported.

These are all very serious side effects.

If you experience these side effects, you have hypersensitivity to MOMETIX AQ. You may need to get immediate medical help.

Other side effects

Side effects are defined as shown in the following categories:

Very common: It occurs in at least 1 out of 10 patients

Common: Less than one in 10 patients, but more than one in 100 patients.

Uncommon: less than one in 100 patients, but more than one in 1000 patients.

Rarely: less than one in 1,000 patients may be seen, but more than one in 10,000 patients.

Very rare: Less than one in 10,000 patients can be seen.

Unknown: Unable to estimate from the available data.

Side effects which have been reported from adults and adolescence who have an allergic rhinitis in clinical studies are given below:

Common:

- epistaxis (nose bleeding),
- pharyngitis (throat inflammation),
- nasal burning,
- nasal irritation,
- nasal ulceration (ulceration at nose),
- sneezing,
- headache.

Unknown:

- Growth reduction in children receiving long term treatment,
- Visual disturbances due to increase in pressure in the eye (glaucoma)

Regular follow-up of the height of children receiving long-term treatment with nasal corticosteroids is recommended.

Epistaxis (nose bleeding) is generally mild and heals by itself. The incidence is 5% higher when compared to placebo (no active substance), but when compared to active control nasal corticosteroids, it is comparable or lower (up to 15%). Incidences of the all other effects are at the comparable level with the placebo.

The incidence of side effects in pediatric patients, e.g. Headache (3%), epistaxis (6%), nasal irritation (2%) and sneezing (2%) were comparable to placebo.

Nasal polyps (benign tumour): Incidence of the side effects are comparable with the placebo and similar with the side effects on people who has allergic rhinitis. Side effects which are reported during the clinical studies on nasal polyps treatment are given below:

Very common: Nose bleeding is very common with 200 mcg twice daily

Common: Upper respiratory infection is common with 200 micrograms once a day, nasal bleeding with 200 micrograms once a day, throat irritation with 200 micrograms twice daily, headache with 200 micrograms once daily and 200 micrograms twice daily.

Uncommon: Upper respiratory infection is uncommon with 200 micrograms twice daily

Very rarely, taste and odor disturbances have been reported.

Nasal septum perforation (nasal cartilage) or increased intraocular pressure and / or cataracts have been reported after intranasal corticosteroids.

The effects of nasal corticosteroids on the whole body can be seen especially when prescribed at high doses over long periods.

5. HOW TO STORE MOMETIX AQ?

Keep MOMETIX AQ out of the reach of children and in its packaging.

Store at room temperature below 25°C. Do not freeze it.

Use in accordance with expiration dates.

Do not use MOMETIX AQ after the expiry date which is stated on the bottle and carton.

Do not use MOMETIX AQ if you notice defects in the product and / or packaging.

Do not dispose of expired or unused medicines! Hand over to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder:

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Site of Manufacturing:

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