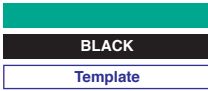


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MOMETASONE FUROATE 50 micrograms/actuation NASAL SPRAY, SUSPENSION

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.
- 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.
- 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.

WHAT IS IN THIS LEAFLET:

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

1 What Mometasone Furoate Nasal Spray is and what it is used for

What is Mometasone Furoate Nasal Spray?

Mometasone Furoate 50 micrograms/actuation Nasal Spray, Suspension contains mometasone furoate, one of a group of medicines called corticosteroids. Mometasone Furoate should not be confused with “anabolic” steroids misused by some athletes and taken as tablets or injections. When tiny amounts of mometasone furoate are sprayed into the nose, it can help to relieve inflammation, sneezing, itching and a blocked up or runny nose.

What is Mometasone Furoate Nasal Spray used for?

Mometasone Furoate Nasal Spray is used in adults and children aged 6 years and older to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial rhinitis.

In adults aged 18 years and over, Mometasone Furoate Nasal Spray is also used to treat nasal polyps.

What is hayfever and perennial rhinitis?

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. These allergies cause a runny nose and sneezing and make the lining of the nose swell, causing a stuffy blocked-up feeling. Mometasone Furoate Nasal Spray reduces the swelling and irritation in your nose and so relieves sneezing, itching and a blocked-up or runny nose.

What are nasal polyps?

Nasal polyps are small growths on the lining of the nose and usually affect both nostrils. The main symptom is a blocked feeling in the nose, which may affect breathing through the nose. Watering from the nose, a feeling of something running down the back of the throat and loss of taste and smell may also occur. Mometasone Furoate Nasal Spray reduces the inflammation in the nose, causing the polyps to gradually shrink.

You must talk to your doctor if you do not feel better or if you feel worse after a few days.

2 What you need to know before you use Mometasone Furoate Nasal Spray

Do not use Mometasone Furoate Nasal Spray

- 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 infection in your nose. 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 wait until it has healed before you start using the nasal spray.

Warnings and precautions

Talk to your doctor or pharmacist before using Mometasone Furoate Nasal Spray.

Take special care with Mometasone Furoate Nasal Spray:

- if you have or have ever had tuberculosis
- if you have herpes simplex (virus) infection of the eye
- if you have any other type of infection

- if you are taking other corticosteroid medicines, either by mouth or by injection
- if you have cystic fibrosis

Patients who are immunosuppressed and are using Mometasone Furoate Nasal Spray should avoid coming into contact with anyone who has measles or chickenpox. You should then tell your doctor if you do come into contact with anyone who is suffering from these infections.

Children and adolescents

Sometimes, nasal corticosteroids may affect the growth of children and adolescents. The doctor will monitor the height of children who are receiving prolonged treatment with nasal corticosteroids and may reduce the dose if growth is slowed.

Do not give this medicine to children less than 6 years, as its safety and method of working have not yet been established.

Other medicines and Mometasone Furoate Nasal Spray

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.

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 Mometasone Furoate Nasal Spray. 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. If these occur you should inform your doctor who will advise about continuing use of your nasal spray. 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 and you are worried, you should see your doctor.

Pregnancy, breast-feeding and fertility

You should not use Mometasone Furoate Nasal Spray if you are pregnant unless your doctor has told you to. Tell your doctor if you are pregnant before you start using this medicine. You should not breast-feed when you are using this medicine unless your doctor has told you to.

Important information about some of the ingredients of Mometasone Furoate Nasal Spray

Mometasone Furoate Nasal Spray contains the ingredient benzalkonium chloride solution (20 micrograms per actuation), which is an irritant and may cause skin reactions. If used for longer periods, the preservative benzalkonium chloride may cause nasal mucosa swelling. In case of such a reaction (persistently congested nose) medicinal products for nasal use without benzalkonium chloride should be used if possible. Unless such products are available another pharmaceutical form should be taken.

3 How to use Mometasone Furoate Nasal Spray

Always use Mometasone Furoate Nasal Spray exactly as your doctor has told you. 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 your doctor tells you to.

• Hayfever and perennial rhinitis

Adults and children 12 years of age and older

The recommended dose is two sprays into each nostril once a day for adults (including the elderly) and children 12 years of age and older.

- Once your symptoms are under control, your doctor may advise you to only spray once into each nostril once a day.
- If you do not start to feel any better, you should see your doctor who may tell you to increase the dose to the maximum daily dose of four sprays into each nostril once a day. Once your symptoms are controlled your doctor may advise you to reduce the dose to two sprays into each nostril once daily.

Children aged 6 to 11 years

The recommended 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 you suffer badly from hayfever, your doctor may tell you to start using Mometasone Furoate two to four weeks before the start of the pollen season, as this will help to prevent your hayfever symptoms from occurring. Your doctor may recommend that you use other treatments with Mometasone Furoate, particularly if your eyes are itching or irritated. At the end of the pollen season your hayfever symptoms should get better and treatment may then not be needed.

• Nasal Polyps

The recommended starting dose for 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 should ask you to reduce your dose to the lowest amount where symptoms are still controlled.

- 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 Mometasone Furoate Nasal Spray.

Preparing your nasal spray for use

Your Mometasone Furoate 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:

1. Gently shake the bottle.
2. Put your forefinger and middle finger either side of the nozzle and your thumb underneath the bottle. **Do Not** pierce the nasal applicator.
3. Point the nozzle away from you and then press down with your fingers to pump the spray.

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.

At the normal dose of two sprays into each nostril once daily for the treatment of hayfever and perennial rhinitis and nasal polyps, this product should provide enough doses for 15 days (for the bottle containing 60 metered sprays) and 35 days (for the bottle containing 140 metered sprays).

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

If you use more Mometasone Furoate Nasal Spray than you should
Tell your doctor if you accidentally use more than you were told.

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 Mometasone Furoate Nasal Spray

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 Mometasone Furoate Nasal Spray

In some patients Mometasone Furoate Nasal Spray 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 told to do so by your doctor.

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.

Rarely (may affect up to 1 in 1,000 people), immediate hypersensitivity (allergic) reactions may occur after use of this product. Very rarely (may affect up to 1 in 10,000 people), these reactions may be severe. If you

have any wheezing or have trouble breathing, **get immediate medical help.**

In rare cases, treatment with corticosteroid nasal sprays like Mometasone Furoate has led to an increase in pressure in the eye (glaucoma) and/or cataracts, causing visual disturbances. Contact your doctor if you notice any of these side effects.

Most people do not have any problems after using the nasal spray. The following side effects have been reported:

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

- headache
- sneezing and irritation/burning sensation of the nose
- nose bleeds
- sore nose or throat.

Very rarely (may affect up to 1 in 10,000 people)

- alterations in taste or smell.

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

Mometasone Furoate Nasal Spray contains benzalkonium chloride, which may cause nasal irritation.

Additional side effects in children and adolescents

The frequency and type of side effects in children are expected to be the same as adults. When used at high doses for long periods of time, corticosteroid nasal sprays may cause certain side-effects, such as growth reduction in children. It is recommended that the height of children receiving long-term treatment with nasal corticosteroids is regularly monitored and if any changes are noted, their doctor should be notified.

Reporting of Side Effects

If you get any side effects, talk to your doctor or pharmacist. 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Mometasone Furoate

Keep this medicine out of the sight and reach of children.

Do not use Mometasone Furoate Nasal Spray 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 store above 25°C. Do not freeze.

The spray should be used within 8 weeks of first use.

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 to protect the environment.

6 Contents of the pack and other information

What Mometasone Furoate Nasal Spray contains

- The active substance is mometasone furoate. Each spray (0.1 ml) delivers 50 micrograms of mometasone furoate (as the monohydrate). The total weight of one spray is 100 mg.
- The other ingredients are microcrystalline cellulose and carmellose sodium, glycerol, sodium citrate dihydrate, citric acid monohydrate, polysorbate 80, benzalkonium chloride solution (see section 2) and water for injection.

What Mometasone Furoate Nasal Spray looks like and contents of the pack

Mometasone Furoate is a nasal spray suspension.

Each bottle contains 60, 120 or 140 sprays.

Bottles containing 60 or 120 sprays are supplied in single packs.

Bottles containing 140 sprays are supplied in packs of 1, 2 or 3 nasal sprays. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Teva UK Limited, Eastbourne, BN22 9AG, UK

Manufacturer:

Teva Czech Industries s.r.o

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