

Package leaflet: Information for the user

Mometasone Furoate Teva 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.

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

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

What is Mometasone Furoate Teva Nasal Spray?

Mometasone Furoate Teva 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 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 Mometasone Furoate Teva Nasal Spray used for?

Hayfever and perennial rhinitis

Mometasone Furoate Teva Nasal Spray is used to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial rhinitis in adults and children aged 3 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. Mometasone Furoate Teva Nasal Spray 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.

Nasal polyps

Mometasone Furoate Teva Nasal Spray is used to treat nasal polyps in adults aged 18 and older.

Nasal polyps are small growths on the lining of the nose and usually affect both nostrils. Mometasone Furoate Teva Nasal Spray reduces the inflammation in the nose, causing the polyps to gradually shrink, thereby relieving a blocked feeling in the nose which may affect breathing through the nose.

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

Do not use Mometasone Furoate Teva Nasal Spray

- if you are allergic 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 Mometasone Furoate Teva Nasal Spray 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.

Warnings and precautions

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

- 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 Mometasone Furoate Teva Nasal Spray, 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 who has 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 are using the medicine for several months or longer.
- if you have a persistent irritation to the nose or throat.

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.

If your eyes are itching or irritated, your doctor may recommend that you use other treatments with Mometasone Furoate Teva Nasal Spray.

Contact your doctor if you experience blurred vision or other visual disturbances.

Children

When used at high doses for long periods of time, corticosteroid nasal sprays may cause certain side-effects, such as slowed growth rate 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.

Other medicines and Mometasone Furoate Teva Nasal Spray

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained 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 Mometasone Furoate Teva 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. 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 see your doctor.

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

Pregnancy, breast-feeding and fertility

There is little or no information on the use Mometasone Furoate Teva Nasal Spray in pregnant women. It is not known if mometasone furoate is found in breast milk.

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

Driving and using machines

There is no known information on the effect of Mometasone Furoate Teva Nasal Spray on the ability to drive or use machinery.

Mometasone Furoate Teva Nasal Spray contains benzalkonium chloride

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

3. How to use Mometasone Furoate Teva Nasal Spray

Always use this medicine 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.

Treatment of Hayfever and Perennial Rhinitis

Use in adults and children over 12 years old

The recommended dose is two sprays into each nostril once a day.

In some patients Mometasone Furoate Teva Nasal Spray begins to relieve symptoms within 12 hours after first dose; however, full benefit of treatment may not be seen in the first two days. Therefore, you should continue regular use to achieve full benefit of treatment.

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

Use in children aged 3 to 11 years

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

If you or your child suffer badly from hayfever, your doctor may tell you to start using Mometasone Furoate Teva before the start of the pollen season, as this will help to prevent your hayfever symptoms from occurring. At the end of the pollen season your hayfever symptoms should get better and treatment may then not be needed.

Nasal Polyps

Use in adults over 18 years old

The recommended starting dose 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 Teva Nasal Spray.

Preparing your nasal spray for use

Your Mometasone Furoate Teva 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 10 times until a fine mist is produced.

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.

How long will your nasal spray last

At the dose of two sprays into each nostril once daily, this product should provide enough doses for 15 days (for the bottle containing 60 metered sprays), 30 days (for the bottle containing 120 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, if applicable.
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 the dust cap and nozzle to dry in a warm place.
- Push the nozzle back onto the bottle and replace the dust cap.
- The spray will need to be primed again with 2 sprays when first used after cleaning.

If you use more Mometasone Furoate Teva 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 Teva 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 Teva Nasal Spray

In some patients Mometasone Furoate Teva 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 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 product. These reactions may be severe. You should stop taking Mometasone Furoate Teva Nasal Spray 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.

Other side effects

Most people do not have any problems after using the nasal spray. However, some people, after using Mometasone Furoate Teva Nasal Spray or other corticosteroid nasal sprays, may find that they suffer from:

Common side effects (may affect up to 1 in 10 people)

- headache
- sneezing and irritation/burning sensation of the nose
- nose bleeds [occurred very commonly (may affect more than 1 in 10 people) in people with nasal polyps receiving Mometasone Furoate Teva Nasal Spray 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 available data):

- increase in pressure in the eye (glaucoma) and/or cataracts causing visual disturbances
- damage to the partition in the nose that separates the nostrils
- changes in taste or 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mometasone Furoate Teva Nasal Spray

- 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 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 Teva 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 (see section 2) and water for injection.

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

Mometasone Furoate Teva 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

The marketing authorisation holder is:

Teva Pharma B.V., Swensweg 5, 2031GA Haarlem, The Netherlands.

The manufacturer is:

Teva Czech Industries s.r.o., Ostravská 29, č.p. 305, 747 70 Opava - Komárov, Czech Republic.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria – Mometason Ratiopharm 50 µg/Dosis Nasenspray

Belgium – Mometasone Teva 50 microgram per verstuiving, neusspray, suspensie

Bulgaria – Mometasone Teva

Cyprus – Mometasone Teva 50 mcg/ψεκασμό Ρινικό εκνέφωμα, εναιώρημα

Germany – Mometasonfuroat AbZ 50 Mikrogramm/Sprühstoß Nasenspray, Suspension

Denmark – Mometasonfuroat Teva

Estonia – Mometasone Teva

Greece – Mometasone Teva 50 mcg/ψεκασμό Ρινικό εκνέφωμα, εναιώρημα

Spain – Mometasona Teva 50 microgramos suspensión para pulverización nasal EFG

Finland – Momesonex 50 mikrog/annos nenäsumute, suspensie

France – MOMETASONE TEVA 50 microgrammes/dose, suspension pour pulvérisation nasale

Hungary – Nasotasone 50 mcg szuszpenziós adagolt orrspray

Ireland – Mometasone Furoate Teva 50 micrograms/actuation Nasal Spray, Suspension

Iceland – Momesonex 50 míkrogrömm/skammt nefúði, dreifa

Italy – Mometasone TEVA

Lithuania – Mometasone Teva 50 mikrogramų/dozėje nosies purškalas (suspensija)

Latvia – Mometasone Furoate Teva 50 mikrogrami/izsmidzinājuma deguna aerosols, suspensija

The Netherlands – Mometasonfuroaat Teva 50 microgram/verstuiving, neusspray, suspensie

Poland – Pronasal

Portugal – Mometasona Teva

Sweden – Mometasone Teva 50 mikrogram/dos nässpray, suspension

Slovenia – Mometazonfuroat Teva Pharma 50 mikrogramov/vpih pršilo za nos, suspenzija
United Kingdom – Mometasone Furoate 50 micrograms/actuation Nasal Spray, Suspension

This leaflet was last revised in April 2017.