

Package leaflet: Information for the user

Mometason Apofri 50 micrograms/actuation, Nasal Spray, Suspension

Mometasone Furoate

Please 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 Mometason Apofri is and what it is used for
2. What you need to know before you use Mometason Apofri
3. How to use Mometason Apofri
4. Possible side effects
5. How to store Mometason Apofri
6. Contents of the pack and other information

1. What Mometason Apofri is and what it is used for

What is Mometason Apofri?

Mometason Apofri 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.

What is Mometason Apofri used for?

Hay fever and perennial rhinitis (allergies such as dust mites and animal hair)

Mometason Apofri is used to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial rhinitis in adults and children aged 3 and older.

Hay fever, 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), feather and certain foods. Mometason Apofri reduces the swelling and irritation in your nose and thereby relieving sneezing, itching and a blocked-up or runny nose caused by hay fever or perennial rhinitis.

Nasal polyps

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

Nasal polyps are small growths on the lining inside the nose and usually affect both nostrils. Mometason Apofri 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 Mometason Apofri

Do not use Mometason Apofri

- 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 Mometason Apofri 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 wait until your nose has healed before you start using the nasal spray.

Warnings and precautions

Talk to your doctor or pharmacist before using Mometason Apofri:

- if you have or have ever had tuberculosis.
- 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.

While you are using Mometason Apofri, 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 with 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 persistent irritation to the nose or throat.

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

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 Mometason Apofri.

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 Mometason Apofri

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

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 Mometason Apofri. 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 and you are worried, you should see your doctor.

Some medicines may increase the effects of Mometason Apofri 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

There is little or no information on the use of Mometason Apofri 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 using this medicine.

Driving and using machines

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

Mometason Apofri contains benzalkonium chloride

Mometason Apofri contains 0.02 mg benzalkonium chloride per dose. Benzalkonium chloride may cause irritation and swelling inside the nose, especially if used for a long time.

3. How to use Mometason Apofri

Always use Mometason Apofri exactly as your doctor has told you. You should 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 Hay fever and Perennial Rhinitis (allergies such as dust mites and animal hair)**Use in adults and children over 12 years old**

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

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

In some patients Mometason Apofri begins to relieve symptoms within 12 hours after the 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.

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

Nasal Polyps**Use in adults over 18 years old**

The usual 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 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.

Preparing your nasal spray for use

Your Mometason Apofri 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. Shake the bottle well.
2. Put your forefinger and middle finger either side of the nozzle and your thumb underneath the bottle (Figure 1).
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.

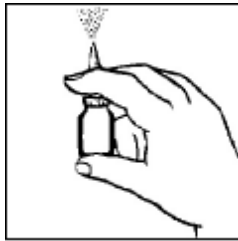


Figure 1

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 normal dose of 2 sprays into each nostril once daily, this product should provide enough doses for 15 days (bottle containing 60 sprays), 30 days (bottle containing 120 sprays) or 35 days (bottle containing 140 sprays).

How to use your nasal spray

1. Shake the bottle well and remove the dust cap. (Figure 2)

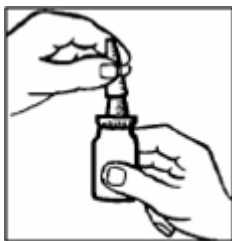


Figure 2

2. Gently blow your nose.
3. Close one nostril and put the nozzle into the other nostril.
4. Tilt your head forward slightly, keeping the bottle upright.
5. 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 (Figure 3).

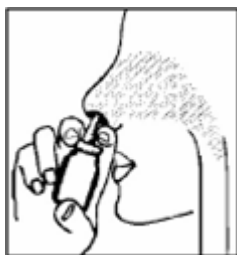


Figure 3

6. Breathe out through your mouth. Repeat step 5 to inhale a second spray in the same nostril.

7. Remove the nozzle from this nostril and breathe out through the mouth.
8. Repeat steps 3 to 6 for the other nostril.

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 for it to 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. 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 re-primed with 2 sprays when first used after cleaning.

If you use more Mometason Apofri 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 Mometason Apofri

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 Mometason Apofri

In some patients Mometason Apofri 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 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 Mometason Apofri 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 Mometason Apofri or other corticosteroid nasal sprays, may find that they suffer from the following side effects:

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

- headache
- sneezing
- nose bleeds [occurred very commonly (may affect more than 1 in 10 people) in people with nasal polyps receiving Mometason Apofri 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 the available data):

- increase in pressure in the eye (glaucoma) and/or cataracts causing visual disturbances
- blurred vision
- damage to the partition in the nose which separates the nostrils
- changes in taste and smell
- difficulty in breathing and/or wheezing.

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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mometason Apofri

- Keep this medicine out of the sight and reach of children.
- Do not use Mometason Apofri after the expiry date which is stated on the bottle and carton. The expiry date refers to the last day of the month.

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 protect the environment.

6. Contents of the pack and other information

What Mometason Apofri contains

- The active substance is mometasone furoate. Each delivered spray (actuation) contains 50 micrograms of mometasone furoate (as mometasone furoate monohydrate).
- The other ingredients are microcrystalline cellulose and carmellose sodium, glycerol, citric acid monohydrate, sodium citrate, polysorbate 80, benzalkonium chloride, purified water.

What Mometason Apofri looks like and contents of the pack

Mometason Apofri nasal spray is a nasal spray suspension packaged in a white plastic bottle with a spray pump.

8. 1 bottle contains 10.0 g nasal spray, suspension, which is equivalent to 60 actuations. Also available in packs of 2 x 60 and 3 x 60 actuations.
9. 1 bottle contains 16.0 g nasal spray suspension, which is equivalent to 120 actuations. Also available in packs of 2 x 120 and 3 x 120 actuations.
10. 1 bottle contains 18.0 g nasal spray suspension, which is equivalent to 140 actuations. Also available in packs of 2 x 140 and 3 x 140 actuations.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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

[To be completed nationally]

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