

Package leaflet: Information for the user

Mometasone Furoate 50 micrograms/actuation nasal spray, suspension (mometasone furoate as the monohydrate)

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 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, suspension is and what it is used for
2. What you need to know before you use Mometasone Furoate nasal spray, suspension
3. How to use Mometasone Furoate nasal spray, suspension
4. Possible side effects
5. How to store Mometasone Furoate nasal spray, suspension
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1. What Mometasone Furoate nasal spray, suspension is and what it is used for

Mometasone Furoate nasal spray, suspension contains the active ingredient mometasone furoate (as the monohydrate). Mometasone furoate is a corticosteroid (steroid for short) which has an anti-inflammatory action, reducing swelling and irritation which causes sneezing, itching and a blocked or runny nose.

What is Mometasone Furoate nasal spray, suspension used for?

Hay fever and perennial rhinitis

This medicine 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. This medicine 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

This medicine is used to treat nasal polyps in adults aged 18 and over.

Nasal polyps are small growths on the lining of the nose and usually affect both nostrils. This medicine 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 nasal spray, suspension

Do not use Mometasone Furoate nasal spray, suspension

- if you are **allergic** (hypersensitive) to mometasone furoate or to any of the other ingredients of this medicine (listed in section 6).
- if you have an untreated **infection** in your nose. Use of this medicine 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, pharmacist or nurse before using Mometasone Furoate nasal spray, suspension if you:

- have or have ever had **tuberculosis**.
- have any **other type of infection**.
- are taking other **corticosteroid medicines**, either by mouth or by injection.
- have **cystic fibrosis**.

While you are using Mometasone Furoate nasal spray, suspension, 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.

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 this medicine.

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, you should notify your doctor.

Other medicines and Mometasone Furoate nasal spray, suspension

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 Mometasone Furoate nasal spray, suspension. 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 contact your doctor.

Pregnancy and breast-feeding and fertility

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.

There is little or no information on the use of Mometasone Furoate nasal spray, suspension in pregnant women. It is not known if mometasone furoate is found in breast milk.

Driving and using machines

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

Mometasone Furoate nasal spray, suspension contains benzalkonium chloride

This medicine contains benzalkonium chloride which may cause skin reactions or nasal irritation.

3. How to use Mometasone Furoate nasal spray, suspension

Always use this medicine exactly as your doctor or pharmacist 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

- 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 age 3 – 11 years of age

The recommended dose is ONE spray into each nostril ONCE a day.

If you or your child suffer badly from hayfever, your doctor may tell you to start using Mometasone Furoate nasal spray, suspension 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.

For 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 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

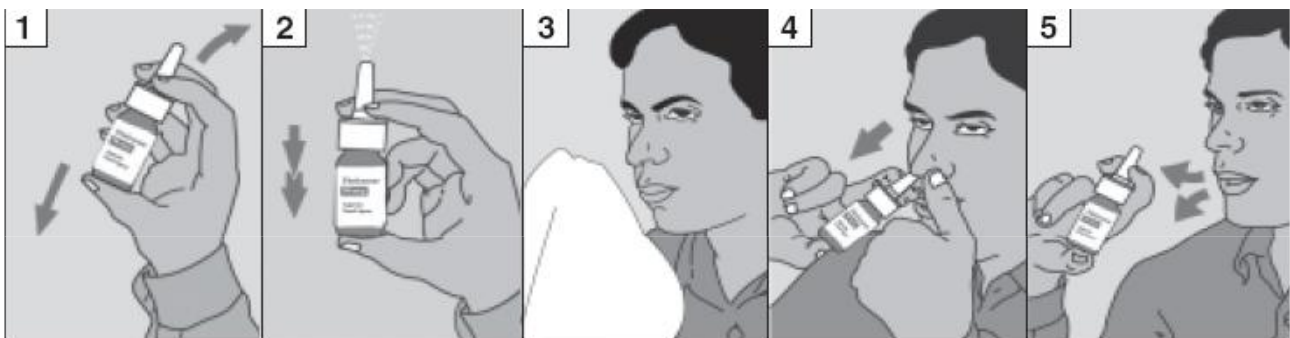
If you are using the nasal spray for the first time, you should prime the pump by pumping the spray 10 times until a fine mist is produced. To do this:

1. Gently shake the bottle
2. Put your forefinger and middle finger on the collar either side of the nozzle and your thumb underneath the bottle.
3. Keep the thumb still and press down with your fingers to pump the spray, holding the nozzle away from you.

If you have not used the nasal spray for 14 days or longer, you should re-prime the pump by pumping the spray 2 times until a fine mist is produced.

If there is no spray and you think the nozzle may be blocked, clean it. (Refer to cleaning instructions below). **DO NOT** try to unblock the spray hole with a pin or other sharp object as this will destroy the spray mechanism.

How to use your nasal spray



1. Shake the bottle gently.
2. Remove the dust cap.
3. Blow your nose gently.
4. Hold the bottle as shown. Place your finger on your nose to close one nostril, and put the nozzle in your other nostril. Tilt your head forward and keep the bottle upright. Start to breathe in slowly through your nose and at the same time press down firmly on the collar of the bottle with your finger, which releases a spray of mometasone furoate.
5. Breathe out through your mouth. Repeat step 4 if more than one spray is required into the same nostril. Remove the nozzle from the nostril and breathe out through your mouth.

Repeat steps 4 to 5 for the other nostril.

After using the spray, wipe the nozzle carefully with a clean tissue and replace the dust cap.

Cleaning your Mometasone Furoate nasal spray, suspension bottle

1. Clean your nasal spray at least once a week as it can become blocked, stopping it from working properly.
2. Remove the dust cap.

3. Gently pull upwards on the white collar to remove the nozzle.
4. Soak the nozzle and dust cap in warm water for a few minutes, and then rinse under a running tap.
5. Allow to dry in a warm place before putting back together. Do not dry near a very hot place.
6. Re-fit the nozzle and 'prime' the bottle if necessary by pumping the spray a few times to produce a fine mist.
7. 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.

If you use more Mometasone Furoate nasal spray, suspension than you should

If you accidentally use more than your prescribed dose of Mometasone Furoate nasal spray, suspension tell your doctor as soon as possible.

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, suspension

If you forget a dose of Mometasone Furoate nasal spray, suspension, use it as soon as you remember, then carry on as before. Do not use an extra dose to make up for the one that you missed.

If you stop using Mometasone Furoate nasal spray, suspension

In some patients this medicine 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, pharmacist or nurse.

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 this medicine 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 this medicine or other corticosteroid nasal sprays, may find that they suffer from:

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 this medicine 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,
- 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, 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 nasal spray, suspension

Keep this medicine out of sight and reach of children.

Do not store above 25°C.

Do not freeze.

Store in the original container.

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 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.

Use within 2 months of first use

6. Contents of the pack and other information

What Mometasone Furoate nasal spray, suspension contains

- The active substance is mometasone furoate. Each actuation delivers 50 micrograms of mometasone furoate (as the monohydrate) as delivered dose (ex actuator).
- The other ingredients are glycerol, microcrystalline cellulose, carmellose sodium, citric acid monohydrate, polysorbate 80, benzalkonium chloride, sodium citrate dihydrate, water for injection.

What Mometasone Furoate nasal spray, suspension looks like and contents of the pack

One white opaque plastic vial, fitted with a white-metered atomising pump, white nasal adaptor and a translucent dust cap for nozzle.

Each bottle of Mometasone furoate 50 micrograms/actuation nasal spray, suspension provides 140 sprays. Each actuation delivers a dose of 50 micrograms of mometasone furoate (as the monohydrate).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Cipla (EU) Limited, Hillbrow House, Hillbrow Road,
Esher, Surrey, KT10 9NW, United Kingdom

Manufacturer:

Pharmadox Healthcare Ltd., KW20A Kordin Industrial Park,
Paola, PLA 3000, Malta

S&D Pharma CZ, spol. s r.o., Theodor 28, Pchery (Pharmos a.s. facility), 273 08, Czech Republic

Cipla (EU) Limited, 4th Floor, 1 Kingdom Street, London, W2 6BY, United Kingdom

Cipla Europe NV, Uitbreidingstraat 80, 2600 Antwerp, Belgium

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

United Kingdom	Mometasone furoate 50 micrograms/actuation Nasal Spray, Suspension
Bulgaria	Мометазонов фуروات Сипла 50 микрограма / впръскване спрей за нос, суспензия
Slovak Republic	Mometasone furoate Cipla 50 mikrogramov nosová suspenzná aerodisperzia
Estonia	Mometasone Cipla
Greece	Mometasone furoate Cipla 50 μικρογραμμάρια / ενεργοποίηση, Ρινικό εκνέφωμα, εναιώρημα
Iceland	Mometasone furoate Cipla 50 míkrogrömm/úðaskammt nefúði, dreifa
Netherlands	Mometasonfuroaat Cipla 50 microgram/ verstuiving neusspray, suspensie
Romania	Mometazonă furoat Cipla 50 micrograme/doza, spray nazal, suspensie
Malta	Mometasone furoate 50 micrograms/actuation Nasal Spray, Suspension
Cyprus	Mometasone furoate Cipla 50 μικρογραμμάρια / ενεργοποίηση, Ρινικό εκνέφωμα, εναιώρημα
Ireland	Mometasone furoate 50 micrograms/actuation nasal spray, suspension
Luxembourg	Mometasone furoate Cipla 50 microgrammes/ pulvérisation, suspension pour pulvérisation nasale
Czech Republic	Mometason furoát Cipla 50 mikrogramů/dávku
Poland	Nasehaler
Portugal	Mometasona Generis

This leaflet was last revised in 12/2015.