

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation)

Mometasone Furoate (50mcg/actuation)

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What Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) is used for

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) contains mometasone furoate, one of a group of medicines called corticosteroids.

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) is used in adults, adolescents and children between the ages of 3 and 11 years to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial rhinitis. In adults and adolescents aged 18 and over, Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) is also used to treat nasal polyps. In patients aged 12 and over without signs or symptoms of severe bacterial infection, Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) is used to treat acute rhinosinusitis.

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. Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) 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. Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) reduces the inflammation in the nose, causing the polyps to gradually shrink.

What is Rhinosinusitis?

Rhinosinusitis is the inflammation and blockage of the sinuses behind the nose. Symptoms can include a stuffy or runny nose, feeling of something running down the back of the throat, and facial pressure or pain. Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) relieves these symptoms by reducing the inflammation in the nose in patient with acute rhinosinusitis, without signs and symptoms of severe bacterial infection.

How Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) works

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.

Before you use Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation)

- When you must not use it

- If you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation).
- 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 bleeding tendency or recurring nose bleeds.
- 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.

- Before you start to use it

Tell your doctor or pharmacist about any medical problems, such as

- 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 had recent nasal surgery or trauma.

Discuss them with your doctor before using Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation).

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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 Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation). A few people may find that once they

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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.

Some medicines may increase the effects of Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

Pregnancy and breast-feeding

You should not use Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) 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.

How to use Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation)

- How much to use

Always use Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) 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.

a) Hay fever and perennial rhinitis

Adults and adolescents over 12 years old:

The usual dose is two sprays into each nostril once a day for adults (including the elderly) and

adolescents over the age of 12 years.

- 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 and he 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

Children aged 3 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 you suffer badly from hayfever, your doctor may tell you to start using Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) two to four weeks 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.

b) Nasal Polyps

The usual dose for adults and adolescents aged 18 and over is two sprays into each nostril twice daily

- Once symptoms are under control, your doctor should ask you to reduce your dose to two sprays into each nostril once daily.

c) Acute Rhinosinusitis

The usual dose for adults and adolescents aged 12 and over is two sprays into each nostril twice daily.

- If symptoms get worse during treatment or no improvement seen after 15 days, you should contact your doctor.

- When to use it

Use as directed by your doctor or pharmacist

- How long to use it

Do not use the spray for longer than your doctor tells you.

How should I use Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation)?

i) Preparing your nasal spray for use

Your Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) 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 and remove the dust cap.
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.

ii) How to use your nasal spray

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

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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.

iii) Cleaning your nasal spray

It is important to clean your nasal spray regularly, otherwise it may not work properly.

1. Remove the dust cap and gently pull off the nozzle.

2. 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.**

3. Allow to dry in a warm place.

4. 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 forget to use it

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 use too much (overdose)

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 stop using Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation)

In some patients Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) should begin to relieve symptoms 12 hours after the first dose. 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.

While you are using Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation)

See "*How much to use, When to use it, How long to use it*"

Things you must do

Tell your doctor if you are pregnant or plan to become pregnant.

Tell your doctor if you plan to have or have had a recent nasal surgery or trauma.

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

- Things you must not do

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) is for intranasal use only. Avoid getting it into your eyes. Do not use it to treat anything other than the condition for which it was prescribed.

- Things to be careful of

While using Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation), 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 is suffering from these infections.

Side effects

Like all medicines, Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) can cause side effects, although not everybody gets them.

Rarely, immediate hypersensitivity (allergic) reactions may occur after use of this product. Very rarely, these reactions may be severe. If you have any wheezing or have trouble breathing, get immediate medical help.

In very rare cases, treatment with corticosteroid nasal sprays like Bexomet

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Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) has led to an increase in pressure in the eye (glaucoma), causing visual disturbances and damage to the partition in the nose which separates the nostrils. Contact your doctor if you notice any of these side effects.

Other side effects

Most people do not have any problems after using the nasal spray. However, a few people after using Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) or other corticosteroid nasal sprays may find that they suffer from:

- headache
- sneezing
- nose bleeds
- sore nose or throat
- alterations in taste or smell which may occur very rarely.
- blurred vision

Children

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.

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation)

- Storage

- Keep out of the reach and sight of children.
- Keep in a dry place, below 30°C. Protect from light. Store away from heat. Do not freeze.
- Do not use Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) 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.
- Each bottle should be used within 2 months of first opening. Only open one bottle at a time.

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

A white colored, homogenous, viscous suspension filled in a white opaque high

density 20 ml polyethylene (HDPE) bottle fitted with a crimp on metered dose pump & with a white opaque actuator & transparent dust cap.

- Ingredients

- Active ingredient
Mometasone Furoate Monohydrate

- Inactive ingredients
Glycerol, Microcrystalline Cellulose & Carboxymethylcellulose Sodium (Avicel RC 591), Polysorbate 80, Sodium Citrate, Citric Acid Monohydrate, Benzalkonium Chloride Solution (50%)

- MAL number:

MAL*****

Manufacturer

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BANGLADESH

Product Registration Holder

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