

Monitazone 50mcg/actuation Nasal Spray

Mometasone Furoate (0.5mg/mL)

What is in this leaflet

1. What Monitazone is used for
2. How Monitazone works
3. Before you use Monitazone
4. How to use Monitazone
5. While you are using it
6. Side effects
7. Storage and Disposal of Monitazone
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What is Monitazone used for

Monitazone is indicated in adults, adolescents and children between the ages of 3 and 11 years to treat symptoms of seasonal or perennial rhinitis (inflammation inside the nose) and nasal polyps (growth of tissue in the nose) in patients 18 years of age and older. Monitazone is also indicated for the treatment of symptoms associated with acute rhinosinusitis (inflammation of your nasal passages and sinuses) in adults and children aged 12 years and older without symptoms of severe bacterial infection.

How Monitazone 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 Monitazone

-When you must not use it

If you are allergic to mometasone furoate or any of the other ingredients of Monitazone.

- 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 taking Monitazone. 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 Monitazone.

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 and Lactation:

You should not use Monitazone 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.

-Taking other medications

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

How to use Monitazone

(a) Shake the bottle gently, remove the cap and safety pin like below.

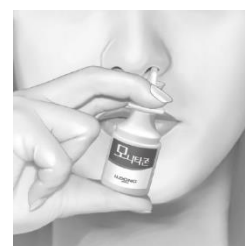


(b) When you use Monitazone for the first time, prime the pump by pressing downward on the nasal applicator using your index finger and middle finger while holding the base of the bottle with your thumb. Press down and release the pump 5 or 10 times until a fine spray appears. If unused for more than 2 weeks, prime the pump again 2 times until a fine spray appears.



(c) Gently blow your nose to clear the nostrils. Close one nostril using your finger and put the nozzle into the other nostril.

(d) Tilt your head forward slightly, keeping the bottle upright.



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(e) 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.

(f) Breathe out through your mouth. Repeat step (e) to inhale a second spray in the same nostril if applicable.

(g) Remove the nozzle from this nostril and breathe out through the mouth.

(h) Repeat steps (c) to (g) for the other nostril. Do not use more than directed number of times.

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

-How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking Monitazone for as long as your doctor recommends.

-If you forget to use it

Take a dose of Monitazone as soon as you remember. However, do not take more than the daily dose prescribed by your doctor.

-If you use too much (overdose)

Contact your doctor immediately

While you are using 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.

-Things you must not do

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

Driving and using machinery:

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

Side effects

Like all medicines, Monitazone 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.

Very common side effects observed: nosebleed.

Common side effects observed: headache, nasal burning/irritation and throat irritation

Glaucoma has been observed as a side-effect of this medication although its occurrence is not well known.

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

Storage and Disposal of product name

-Storage

Store below 30°C. Keep out of reach of children.

-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

White to off-white opaque suspension in a container fitted with a metered spray pump.

-Ingredients

- Active ingredient(s)

Mometasone furoate
- Inactive ingredient(s)

Microcrystalline cellulose and carboxymethylcellulose sodium (avicel), glycerine, citric acid hydrous, sodium citrate dehydrate, polysorbate 80, benzalkonium chloride and purified water

-MAL number

MAL18046159ACZ

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Manufacturer

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Product Registration Holder

Healol Pharmaceuticals Sdn. Bhd.

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