

APO-MOMETASONE FUROATE AQUEOUS NASAL SPRAY 50MCG/METERED SPRAY

Mometasone Furoate (50 µg/spray)

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What Apo-Mometasone is used for

Apo Mometasone is used for the following condition:

- Treatment of symptoms of seasonal or perennial (all year long) rhinitis (inflammation of the lining inside the nose)
- Treatment of nasal polyps (soft and painless growths on the lining of your nasal passages)
- Treatment of symptoms of acute rhinosinusitis (inflammation of nasal passage)
- Prevention of seasonal allergic rhinitis (inflammation of the lining inside the nose due to allergy) symptoms

How Apo-Mometasone works

Apo-Mometasone belongs in the corticosteroid group. It works by reducing inflammation at the affected area, relieving symptoms of the condition mentioned above.

Before you use Apo-Mometasone

- When you must not use it

Do not use this product if you are:

- allergic to mometasone furoate, or any other ingredients in this medicine. (Please refer to **Product Description**)
- if you have an infection in the nose that is not being treated
- if your nose is recently operated or injured
- if you have been diagnosed with tuberculosis

- if you have any known infection, such as untreated fungal, bacterial, systemic viral infections, or herpes simplex.

Pregnancy and lactation

Do not take Apo-Mometasone if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Mometasone if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Before you start to use Apo-Mometasone, your doctor needs to know if you have any other medical condition, especially those which are mentioned above (Refer when you must not use it).

- 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.

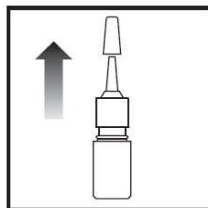
Some medications might cause complication when taken together with Apo-Mometasone, which include CYP3A inhibitors, including cobicistat-containing products.

How to use Apo-Mometasone

- How to use

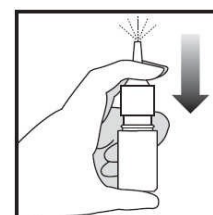
Shake well before each use.

1. Remove the plastic dust cap.

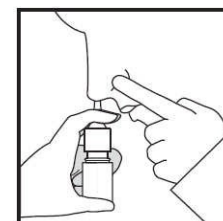


2. The very first time the spray is used; prime the pump by pressing downward on the shoulders of the white

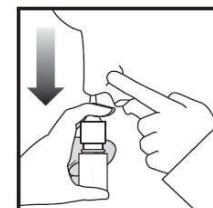
applicator, using your forefinger and middle finger while supporting the base of the bottle with your thumb. Press down and release the pump ten (10) times or until a fine spray appears. The pump is now ready to use. The pump may be stored unused for up to 2 weeks without repriming. If unused for more than 2 weeks, prime the pump again two (2) times, until a fine spray appears.



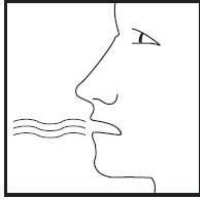
3. Gently blow your nose to clear your nostrils. Close one nostril using your finger. Tilt your head forward slightly and, keeping the bottle upright, carefully insert the nasal applicator into the other nostril.



4. For each spray, press firmly downward once on the shoulder of the white applicator, using your forefinger and middle finger while supporting the base of the bottle with your thumb. Spray while breathing gently inward through the nostril, with the mouth closed.



5. Then breathe out through your mouth. Repeat step 4 to inhale a second spray in the same nostril.



6. Repeat in the other nostril by following step 3 to step 5.

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

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.

- 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.

For treatment of symptoms of seasonal or perennial (all year long) rhinitis (inflammation of the lining inside the nose); **Adults:** the usual recommended dose for prevention and treatment is two sprays (50 mcg/spray) in each

nostril once daily (total dose 200 mcg). Once symptoms are controlled, dose reduction to one spray in each nostril (total dose 100 mcg may be effective for maintenance. **Children between the ages of 3 and 11 years:** The usual recommended dose is one spray (50mcg/spray) in each nostril once daily (total dose 100 mcg). Administration to young children should be aided by an adult.

For treatment of nasal polyps (soft and painless growths on the lining of your nasal passages); **Adults:** The usual recommended dose is two sprays (50 mcg/spray) in each nostril twice daily (total daily dose of 400 mcg). Once symptoms are adequately controlled, dose reduction to two sprays in each nostril once daily (total daily dose 200 mcg) is recommended.

For treatment of symptoms of acute rhinosinusitis (inflammation of nasal passage); **Adults:** The usual recommended dose for acute rhinosinusitis is two actuations (50mcg/spray) in each nostril twice daily (total daily dose of 400 mcg). If no improvement is seen after 15 days of twice daily administration, alternative therapies should be considered. If symptoms worsen during treatment, you should consult 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 Apo-Mometasone for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Mometasone.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Apo-Mometasone to anyone else, even if they have the same symptoms or condition as you.

DO NOT spray this medication into your eye; spray it into your nose cavity only.

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.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the spray makes you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Apo-Mometasone can cause side effects, although not everybody gets them.

Very common side effect that may occur with the use of corticosteroid nasal spray includes:

- Nose-bleed

Common side effects include:

- Sore throat
- Headache
- Nose-bleed
- Nasal burning
- Nasal irritation
- Nasal ulceration
- Throat irritation

Other less common side effects include:

- Hypersensitivity including anaphylactic reactions, swelling of area beneath the skin and difficulty in breathing
- Glaucoma, increased intraocular pressure, cataracts
- Nasal lining perforation
- Disturbances of taste and smell

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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 Apo-Mometasone

- Storage

Keep out of the reach and sight of children.

Store below 30°C and protected from light. Do not freeze.

- 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

Apo-Mometasone comes in a nasal spray device which deliver 140 sprays. Each spray delivers an unscented mist, containing the equivalent of 50 mcg of Mometasone furoate.

- Ingredients

- Active ingredient
Mometasone Furoate
- Inactive ingredients Benzalkonium Chloride Solution, Citric Acid, Glycerin, Microcrystalline Cellulose and Carboxymethyl-cellulose Sodium, Polysorbate 80, Purified Water, Sodium Citrate.

- MAL number:

MAL18016032AZ

Manufacturer

Apotex Inc.-Richmond Hill Site
380 Elgin Mills Road East,
Richmond Hill, Ontario,
Canada L4C 5H2.

Product Registration Holder

Pharmaforte (M) Sdn Bhd,
2, Jalan PJU 3/49,
Sunway Damansara,
47810 Petaling Jaya,
Selangor

Date of revision

2/7/2025

Serial Number

NPRA (R2/1)250701/1497