

PATIENT INFORMATION

Mometasone Furoate Nasal Spray, 50 mcg (moe met' a sone fure' oh ate)

For Nasal Use Only

Read the Patient Information that comes with Mometasone Furoate Nasal Spray before you start using it and each time you get a refill. There may be new information. This Patient Information does not take the place of talking to your healthcare provider about your medical condition or treatment. If you have any questions about Mometasone Furoate Nasal Spray, ask your healthcare provider.

What is Mometasone Furoate Nasal Spray?

Mometasone Furoate Nasal Spray is a man-made (synthetic) corticosteroid medicine that is used to:

- treat the nasal symptoms of seasonal and year-round allergic rhinitis (inflammation of the lining of the nose) in adults and children 2 years of age and older.
 - treat nasal congestion that happens with seasonal allergic rhinitis in adults and children 2 years of age and older.
 - prevent nasal symptoms of seasonal allergic rhinitis in people 12 years of age and older.
 - treat nasal polyps in people 18 years and older.
- It is not known if Mometasone Furoate Nasal Spray is safe and effective in children under:
- 2 years of age to treat allergic rhinitis.
 - 18 years of age to treat nasal polyps.

Who should not use Mometasone Furoate Nasal Spray?

Do not use Mometasone Furoate Nasal Spray if you are allergic to mometasone furoate or any of the ingredients in Mometasone Furoate Nasal Spray. See the end of this leaflet for a complete list of ingredients in Mometasone Furoate Nasal Spray.

What should I tell my healthcare provider before and during treatment with Mometasone Furoate Nasal Spray?

Before you take Mometasone Furoate Nasal Spray, tell your healthcare provider about all of your medical conditions, including if you:

- have had recent nasal sores, nasal surgery, or nasal injury.
- have eye or vision problems, such as cataracts, glaucoma (increased pressure in your eye), and blurred vision, or other changes in your vision.
- have tuberculosis or any untreated fungal, bacterial, viral infections, or eye infections caused by herpes.
- have been near someone who has chickenpox or measles.
- are not feeling well or have any other symptoms that you do not understand.
- **are pregnant or planning to become pregnant.** It is not known if Mometasone Furoate Nasal Spray will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- **are breastfeeding or planning to breastfeed.** It is not known whether mometasone furoate passes into your breast milk.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take:

- certain medicines for HIV (such as ritonavir, atazanavir, indinavir, nelfinavir, and saquinavir)
- cobicistat-containing products
- certain antifungals (such as ketoconazole and itraconazole)
- certain antibiotics (such as clarithromycin and telithromycin)
- certain antidepressants (such as nefazodone)

If you take these medicines with Mometasone Furoate Nasal Spray, your healthcare provider should monitor you for side effects.

Mometasone Furoate Nasal Spray may affect the way other medicines work, and other medicines may affect how Mometasone Furoate Nasal Spray works.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use Mometasone Furoate Nasal Spray?

- Use Mometasone Furoate Nasal Spray exactly as prescribed by your healthcare provider.
- This medicine is for use in the **nose only**. Do not spray it into your mouth or eyes.
- An adult should help a young child use this medicine.
- For best results, you should keep using Mometasone Furoate Nasal Spray regularly each day without missing a dose. If you do miss a dose of Mometasone Furoate Nasal Spray, take it as soon as you remember. However, do not take more than the daily dose prescribed by your healthcare provider.
- Do not use Mometasone Furoate Nasal Spray more often than prescribed. Ask your healthcare provider if you have any questions.
- For detailed instructions on how to use Mometasone Furoate Nasal Spray, see the “Patient Instructions for Use” at the end of this leaflet.
- See your healthcare provider regularly to check your symptoms while taking Mometasone Furoate Nasal Spray and to check for side effects.

What should I avoid while taking Mometasone Furoate Nasal Spray?

If you are taking other corticosteroid medicines for allergy, by mouth or injection, your healthcare provider may advise you to stop taking them after you begin using Mometasone Furoate Nasal Spray.

What are the possible side effects of Mometasone Furoate Nasal Spray?

Mometasone Furoate Nasal Spray may cause serious side effects, including:

- **thrush (candida), a fungal infection in your nose and throat.** Tell your healthcare provider if you have any redness or white colored patches in your nose or throat.
- **hole in the cartilage of the nose (nasal septal perforation).** A whistling sound when you breathe may be a symptom of nasal septum perforation.
- **slow wound healing.** Do not use Mometasone Furoate Nasal Spray until your nose has healed if you have a sore in your nose, if you have surgery on your nose, or if your nose has been injured.
- **eye problems, including glaucoma, cataracts, and blurred vision.** You should have regular eye exams.
- **allergic reactions.** Allergic reactions including wheezing may happen after using Mometasone Furoate Nasal Spray. If wheezing happens stop using Mometasone Furoate Nasal Spray. Tell your healthcare provider or get medical help right away.
- **immune system problems that may increase your risk of infections.** You are more likely to get infections if you take medicines that weaken your immune system. Avoid contact with people who have contagious diseases such as chicken pox or measles while using Mometasone Furoate Nasal Spray. Symptoms of infection may include: fever, pain, aches, chills, feeling tired, nausea, and vomiting. Tell your healthcare provider about any signs of infection while you are using Mometasone Furoate Nasal Spray.
- **adrenal insufficiency.** Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones. Symptoms of adrenal insufficiency can include: tiredness, weakness, nausea and vomiting and low blood pressure.
- **slowed growth in children.** Your child's growth should be checked regularly while using Mometasone Furoate Nasal Spray.

The most common side effects of Mometasone Furoate Nasal Spray include:

- headache
- viral infection
- sore throat
- nosebleeds
- cough

These are not all the possible side effects of Mometasone Furoate Nasal Spray. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Mometasone Furoate Nasal Spray?

- Store Mometasone Furoate Nasal Spray at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].
- Protect from light.

- Avoid prolonged exposure of Mometasone Furoate Nasal Spray container to direct light.
- Shake well before each use.
- **Keep Mometasone Furoate Nasal Spray and all medicines out of the reach of children.**

General information about the safe and effective use of Mometasone Furoate Nasal Spray

Medicines are sometimes prescribed for conditions that are not listed in a Patient Information leaflet. Do not use Mometasone Furoate Nasal Spray for a condition for which it was not prescribed. Do not give Mometasone Furoate Nasal Spray to other people even if they have the same symptoms you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about Mometasone Furoate Nasal Spray that is written for health professionals.

What are the ingredients in Mometasone Furoate Nasal Spray?

Active ingredients: mometasone furoate

Inactive ingredients: benzalkonium chloride, citric acid, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, polysorbate 80 and sodium citrate.

For more information, go to www.apotexcorp.com/products or call 1-800-706-5575.

This Patient Information has been approved by the U.S. Food and Drug Administration

APOTEX INC. MOMETASONE FUROATE NASAL SPRAY 50 mcg

Manufactured by:
Apotex Inc.
Toronto, Ontario
M9L 1T9

Manufactured for:
Apotex Corp.
Weston, FL
33326

Revised: November 2020

Patient Instructions for Use

Mometasone Furoate Nasal Spray, 50 mcg (moe met' a sone fure' oh ate)

For use in your nose only.

Read the Patient Instructions for Use carefully before you start to use your Mometasone Furoate Nasal Spray. If you have any questions, ask your healthcare provider.

Shake the bottle well before each use.

1. Remove the plastic cap (See Figure 1).

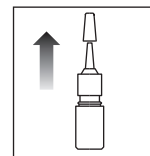


Figure 1

2. Before you use Mometasone Furoate Nasal Spray for the first time, prime the pump by pressing downward on the shoulders of the white nasal applicator using your index finger and middle finger while holding the base of the bottle with your thumb (See Figure 2). **Do Not** pierce the nasal applicator. Press down and release the pump 10 times or until a fine spray appears. **Do Not** spray into eyes. The pump is now ready to use. The pump may be stored unused for up to 1 week without repriming. If unused for more than 1 week, reprime by spraying 2 times or until a fine spray appears.

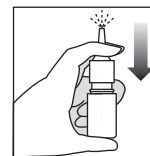


Figure 2

3. Gently blow your nose to clear the nostrils. Close 1 nostril. Tilt your head forward slightly, keep the bottle upright, carefully insert the nasal applicator into the other nostril (See Figure 3). **Do Not** spray directly onto the nasal septum (the wall between the two nostrils).

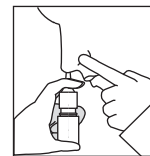


Figure 3

4. For each spray, hold the spray bottle upright and press firmly downward 1 time on the shoulders of the white nasal applicator using your index and middle fingers while supporting the base of the bottle with your thumb. Breathe gently inward through the nostril (See Figure 4).

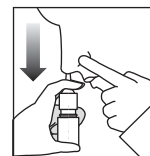


Figure 4

Note: It is important to keep the Mometasone Furoate Nasal Spray unit in an upright orientation (as seen in Figure 4). Failure to do so may result in an incomplete or non-existent spray.

5. Then breathe out through the mouth.

6. Repeat in the other nostril.

7. Wipe the nasal applicator with a clean tissue and replace the plastic cap.

Each bottle of Mometasone Furoate Nasal Spray contains enough medicine for you to spray medicine from the bottle 120 times. Do not use the bottle of Mometasone Furoate Nasal Spray after 120 sprays. Additional sprays after the 120 sprays may not contain the right amount of medicine, **you should keep track of the number of sprays used from each bottle of Mometasone Furoate Nasal Spray**, and throw away the bottle even if it has medicine still left in. **Do not count any sprays used for priming the device.** Talk with your healthcare provider before your supply runs out to see if you should get a refill of your medicine.

Pediatric Use: Administration to young children should be done by an adult. Steps 1 through 7 from the **Patient Instructions for Use**, should be followed.

Cleaning: Do not try to unblock the nasal applicator with a sharp object. Please see **Patient Instructions for Cleaning Applicator**.

Patient Instructions for Cleaning Applicator

1. To clean the nasal applicator, remove the plastic cap (See Figure 5).

2. Pull gently upward on the white nasal applicator to remove (See Figure 6).

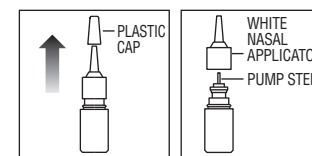


Figure 5

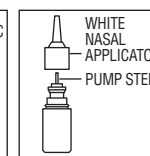


Figure 6

3. Soak the nasal applicator in cold tap water and rinse both ends of the nasal applicator under cold tap water and dry (See Figure 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.

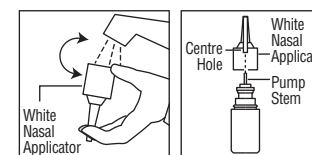


Figure 7

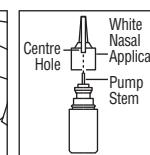


Figure 8

4. Rinse the plastic cap under cold water and dry.

5. Put the nasal applicator back together making sure the pump stem is reinserted into the applicator's center hole (See Figure 8).

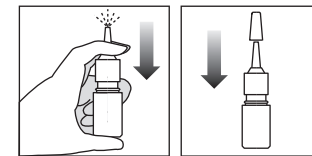


Figure 9

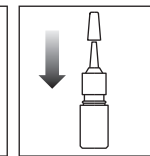


Figure 10

6. Reprime the pump by pressing downward on the shoulders of the white nasal applicator using your index and middle fingers while holding the base of the bottle with your thumb. Press down and release the pump 2 times or until a fine spray appears. **Do Not** spray into eyes. The pump is now ready to use. The pump may be stored unused for up to 1 week without repriming. If unused for more than 1 week, reprime by spraying 2 times or until a fine spray appears (See Figure 9).

7. Replace the plastic cap (See Figure 10).

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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