

Patient Information

NASONEX® [nā-zə-neks] (mometasone furoate monohydrate) **Nasal Spray, 50 mcg**

FOR INTRANASAL USE ONLY

Read the Patient Information that comes with NASONEX 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 NASONEX, ask your healthcare provider.

What is NASONEX?

NASONEX 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.

The safety and effectiveness of NASONEX has not been shown:

- in children under 2 years of age to treat allergic rhinitis.
- in children under 18 years of age to treat nasal polyps.

Who should not use NASONEX?

Do not use NASONEX if you are allergic to any of the ingredients in NASONEX. See the end of this leaflet for a complete list of ingredients in NASONEX.

What should I tell my healthcare provider before using NASONEX?

Before you take NASONEX, tell your healthcare provider if you:

- have had recent nasal sores, nasal surgery, or nasal injury.
- have eye or vision problems, such as cataracts or glaucoma (increased pressure in your eye).
- 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.
- have any other medical conditions.
- **are pregnant or planning to become pregnant.** It is not known if NASONEX will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- **are breastfeeding or planning to breastfeed.** It is not known whether NASONEX passes into your breast milk.

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

NASONEX and other medicines may affect each other and cause side effects. NASONEX may affect the way other medicines work, and other medicines may affect how NASONEX works.

Know the list of medicine you take. Keep a list of your medications with you to show your healthcare provider and pharmacist when a new medication is prescribed.

How should I use NASONEX?

- Use NASONEX 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 NASONEX regularly each day without missing a dose. If you do miss a dose of NASONEX, take it as soon as you remember. However, do not take more than the daily dose prescribed by your doctor.
- Do not use NASONEX more often than prescribed. Ask your healthcare provider if you have any questions.
- For detailed instructions on how to use NASONEX Nasal Spray, see the “**Patient Instructions for Use**” at the end of this leaflet.

See your healthcare provider regularly to assess your symptoms while taking NASONEX and to check for side effects.

What should I avoid while taking NASONEX?

If you are taking other corticosteroid medicines for allergy, either by mouth or injection, your healthcare provider may advise you to stop taking them once you begin using NASONEX.

What are the possible side effects of NASONEX?

NASONEX may cause serious side effects, including:

- **Thrush (*candida*), a fungal infection in your nose and throat.** Tell your doctor if you have any redness or white colored patches in your nose or throat.
- **Slow wound healing. Do not** use NASONEX 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.
- **Some people may have eye problems, including glaucoma and cataracts.** You should have regular eye exams.
- **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 NASONEX. Symptoms of infection may include: fever, pain, aches, chills, feeling tired, nausea and vomiting. Tell your doctor about any signs of infection while you are using NASONEX.
- **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.

The most common side effects of NASONEX include:

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

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of NASONEX. For more information ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NASONEX?

- Store NASONEX at room temperature between 59°F to 86°F (15°C to 30°C).
- Avoid prolonged exposure of NASONEX container to bright light.
- Shake well before each use.

Keep NASONEX and all medicines out of the reach of children.

General information about NASONEX

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

This Patient Information leaflet provides a summary of the most important information about NASONEX. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about NASONEX that is written for health professionals.

For more information, go to www.NASONEX.com or call 1-800-622-4477.

What are the ingredients in NASONEX?

Active Ingredients: mometasone furoate monohydrate

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

Patient Instructions for Use

For use in your nose only.

Read the Patient Instructions for Use carefully before you start to use your NASONEX 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).

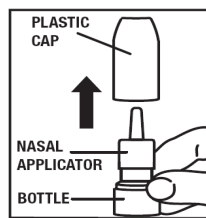


Figure 1

2. Before you use NASONEX 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).

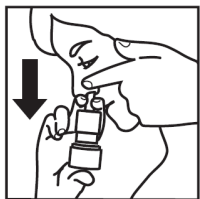


Figure 4

Note: It is important to keep the NASONEX 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 NASONEX Nasal Spray contains enough medicine for you to spray medicine from the bottle 120 times. Do not use the bottle of NASONEX 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 NASONEX 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).

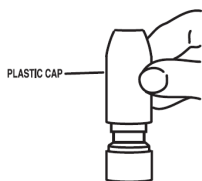


Figure 5

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

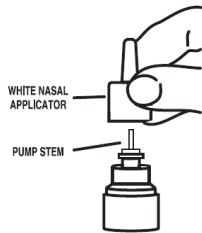


Figure 6

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.**

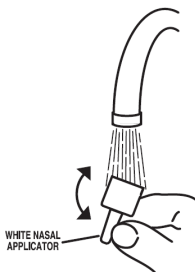


Figure 7

4. Rinse the plastic cap under cold water and dry (See Figure 8).

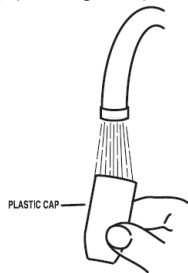


Figure 8

5. Put the nasal applicator back together making sure the pump stem is reinserted into the applicator's center hole (See Figure 9).

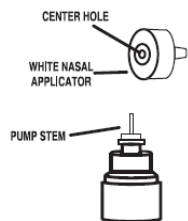


Figure 9

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 10).



Figure 10

7. Replace the plastic cap (**See** Figure 11).



Figure 11

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of
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