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PART III: CONSUMER INFORMATION

Nasonex®

mometasone furoate monohydrate aqueous nasal spray

This leaflet is part III of a three-part "Product Monograph", published when NASONEX® was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about NASONEX®. Please read this leaflet carefully before you start taking NASONEX® and contact your doctor or pharmacist if you have any questions about the medication.

ABOUT THIS MEDICATION

What the medication is used for:
NASONEX® is a corticosteroid, which reduces inflammation. It was prescribed to you by your doctor to treat the symptoms of one of the following conditions:

In adults, adolescents and children between the ages of 3 and 11 years:
Seasonal allergic rhinitis: also called "hay fever" is caused by allergies to grass, pollen, ragweed, etc. Symptoms include stuffiness/congestion in the nose, runny nose, itching and sneezing.
Perennial allergic rhinitis: year round allergies caused by dust mites, animal dander and molds. Symptoms include stuffiness/congestion in the nose, runny nose, itching and sneezing.

In adults and children 12 years of age or older:
Adjunctive treatment to antibiotics in acute episodes of rhinosinusitis, where signs or symptoms of bacterial infection are present: acute rhinosinusitis is the inflammation of the nasal sinuses that may be complicated with a bacterial infection.
NASONEX® is used for the treatment of the inflammatory
component and the antibiotic is used for the infection of the nasal sinuses. Symptoms include (but are not limited to) stuffiness/congestion in the nose, runny nose, feeling of something running down the back of the throat, fever, severe facial/tooth pain (especially on one side of the face), facial swelling or thick nasal discharge with a yellow or green colour. ***Mild to moderate uncomplicated acute rhinosinusitis, where signs or symptoms of bacterial infection are not present:***
NASONEX® is used for the treatment of symptoms related to the inflammation and blockage of the sinuses behind the nose.
Symptoms include stuffiness/congestion in the nose, runny nose, feeling of something running down the back of the throat, and facial pressure or pain. If symptoms get worse or you start to have fever, persistent severe facial/tooth pain (especially on one side of the face), facial swelling or thick nasal discharge with a yellow or green colour, consult your physician immediately.

In adults 18 years of age or older:
Nasal polyps: small growths on the lining of the nose that usually affect both nostrils. The main symptom is a blocked feeling in the nose which may affect breathing through the nose. Other symptoms may include watery nose, a feeling of something running down the back of the throat, loss of taste and smell.
What it does:
When sprayed into the nose it helps reduce symptoms of the conditions listed above.

When it should not be used:
NASONEX® should not be used:
- if you are allergic to NASONEX® or to any of its ingredients.
- if you have an infection in the nose (i.e. yellow or green discharge from the nose) that is not being treated.
- if your nose was recently operated on or injured. In this case you may be told to wait until healing has occurred before using NASONEX®.
- if you have been diagnosed with tuberculosis and it is not being treated.*
- if you have untreated fungal, bacterial, or systemic viral infections.*
- if you have a herpes simplex (virus) infection of the eye and it is not being treated.*

* See WARNINGS AND PRECAUTIONS for additional information.

What the medicinal ingredient is:
NASONEX® contains mometasone furoate monohydrate.

What the nonmedicinal ingredients are:
(alphabetical order): benzalkonium chloride,
carboxymethylcellulose sodium, citric acid, glycerol,
microcrystalline cellulose, polysorbate 80, purified water, and sodium citrate dihydrate.

What dosage forms it comes in:
NASONEX® comes in a nasal spray device which delivers 60 sprays (equivalent to 40 sprays + 20 sprays for the priming and re-priming processes) (sample size), 140 sprays (equivalent to 120 sprays + 20 sprays for the priming and re-priming processes). Each spray delivers an unscented mist, containing the equivalent of 50 mcg of mometasone furoate.
* *Calculated on the anhydrous basis.*

WARNINGS AND PRECAUTIONS

Do not spray NASONEX® into your eyes or mouth. It is for use in the nose only.

Before you use NASONEX® talk to your doctor or pharmacist if you are pregnant or nursing a baby. Breast-feeding is not recommended during treatment with NASONEX®.

Tell your doctor, if you have any of the following conditions before you start using NASONEX® or develop them during treatment. Your doctor may need to lower your dose of this medication, or you may need extra treatment to control the condition. Once advised, your doctor will decide whether any changes in your treatment are needed. In some cases it may be necessary to stop treatment.
- sores in the nose
- tuberculosis (active or previous)
- infection (fungal, bacterial or viral)
- herpes simplex (virus) infection of the eye

(See ABOUT THIS MEDICATION, When it should not be used, for additional information.)

If you think you have developed an infection in the nose after starting NASONEX® (i.e. normally clear discharge from the nose has turned yellow or green) contact your doctor.

If you have been prescribed NASONEX® (but not with antibiotics) for mild-moderate uncomplicated acute rhinosinusitis, consult your doctor if you develop signs or symptoms of bacterial infection (such as fever, persistent severe facial/tooth pain (especially on one side of the face), facial swelling, worsening of symptoms after an initial improvement) or thick nasal discharge with a yellow or green colour.

Be sure to use this medicine exactly as your doctor or pharmacist has instructed. Do not use more NASONEX® than prescribed in an attempt to increase its effectiveness, and do not use this medicine more often than prescribed. Only a physician can prescribe NASONEX® for you. Do not share this medicine with anyone else; it may harm them even if their symptoms are the same as yours. Do not use this product for other disorders.

INTERACTIONS WITH THIS MEDICATION

To avoid the possibility of drug interactions, be sure to advise your physician or pharmacist of any other medications that you are taking, particularly corticosteroid medicine, either by mouth or by injection. The dose of some medications may need adjustment while you are treated with NASONEX®.

Drugs that may interact with NASONEX® are listed below. Your doctor may wish to monitor you carefully if you are taking these medicines:
- Ketoconazole
- Itraconazole,
- Clarithromycin,
- Ritonavir,
- Cobicistat-containing products

PROPER USE OF THIS MEDICATION

DO NOT SPRAY INTO EYES; FOR INTRANASAL USE ONLY.

Usual dose:
In case of severe nasal congestion, your doctor may recommend the use of a nasal decongestant (vasoconstrictor) 2–3 days before NASONEX® to help clear nasal passages and to aid drug delivery.

Treatment of seasonal or perennial allergic rhinitis:
- For children between the ages of 3 and 11 years the usual recommended dose is one (1) spray in each nostril once a day. Young children should be aided by an adult when using NASONEX®.
- For adults (including the elderly) and children 12 years of age and older, the usual recommended dose is two (2) sprays into each nostril once a day. When your symptoms are under control, your physician may recommend one (1) spray into each nostril once daily to maintain control of your symptoms.

Your physician may change this dosage, depending on your response to NASONEX®.

In some patients, NASONEX® may relieve symptoms within 12 hours; others may have to wait at least 48 hours. Full effect depends on regular and continued use (unlike other medications which are used only when necessary). For full benefit of therapy, continue regular use.

Adjunctive treatment to antibiotics in acute episodes of rhinosinusitis:
For adults (including the elderly) and children 12 years of age and older, the usual recommended dose is two (2) sprays into each nostril twice a day.

If needed for better control of your symptoms, your doctor may recommend that the dose be increased to four (4) sprays into each nostril twice daily.

Your physician may change this dosage, depending on your response to NASONEX®.

Treatment of mild to moderate uncomplicated acute rhinosinusitis:
For adults (including the elderly) and children 12 years of age and older, the usual recommended dose is two (2) sprays into each nostril twice a day.

Contact your doctor if symptoms worsen during treatment (see WARNINGS AND PRECAUTIONS).

Treatment of Nasal Polyps:
For adults 18 years and older (including the elderly), the usual recommended dose is two (2) sprays into each nostril twice a day. Once symptoms are controlled, your physician may reduce your dose to two sprays in each nostril once daily.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:
If you miss taking your dose on time, do not worry; take a dose if you remember within an hour or so. However, if you do not remember until later, skip the missed dose and go back to your regular dosing schedule. Do not double the dose.

Directions for Use

DO NOT SPRAY INTO THE EYES. FOR INTRANASAL USE ONLY.

Read complete instructions carefully and use only as directed.

SHAKE WELL BEFORE EACH USE.

1. Remove the teal-blue 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. Do not pierce the nasal applicator. Press down and release the pump 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.
6. Repeat in the other nostril.
7. Replace the plastic dust cap after each use.

The correct amount of medication in each spray can only be assured up to the labeled number of sprays from the bottle even though the bottle may not be completely empty. You should keep track of the number of sprays used from each bottle of NASONEX, and discard the bottle after using the labeled number of sprays. If you have a sample size bottle, it contains 60 sprays (equivalent to 40 sprays + 20 sprays for the priming and re-priming processes).

Cleaning: To clean the nasal applicator, remove the plastic dust cap and pull gently upward on the white nasal applicator so that it comes free. Wash the applicator and dust cap under a cold- water 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.** Dry and replace the nasal applicator followed by the plastic dust cap.

Re-prime the pump with two (2) sprays when first used after cleaning.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects that may occur with the use of corticosteroid nasal sprays, including NASONEX®, are headache, nose-bleed or
blood-tinged mucus, burning or irritation inside the nose, sneezing or sore throat.

Disturbances of taste and smell have been reported very rarely.

The following less common side effects have been seen in Clinical Trials: swollen lymph nodes, vision changes, eye tearing, dry eyes, eye inflammation or infection, ear ache, ringing in the ears, stomach pain, constipation, diarrhea, nausea, tongue and tooth disorders, dry mouth, aggravated allergy symptoms, swelling of the body including the face, fever, flu-like symptoms, thirst, cold sore, infections, muscle and/or joint pain, tremor, dizziness, migraine, depression, nightmares causing sleep disturbances, fatigue, loss of voice, bronchitis, shortness of breath, wheezing, acne, skin rashes and high blood pressure.

In addition to some of the above side effects, the following post- market side effects have been seen: nasal septum perforation.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Rare	Immediate hypersensitivity: an allergic reaction which may cause sudden onset of wheezing or difficulty in breathing shortly after taking this medication			✓
Uncommon	Chest pain, irregular or fast heartbeat			✓
Unknown	Blurred vision, increased pressure in your eyes, eye pain, distorted vision		✓	

IF YOU EXPERIENCE ANY UNDESIRABLE OR TROUBLESOME EFFECTS, INCLUDING ANY THAT ARE NOT LISTED, ADVISE YOUR PHYSICIAN OR PHARMACIST.

HOW TO STORE IT

KEEP OUT OF THE REACH OF CHILDREN.

- Store below 30˚C.
- Protect from light.
- Do not freeze.
- Do not use this product after the expiration date on the package.

When NASONEX® is removed from its cardboard container, prolonged exposure of the product to direct light should be avoided. Brief exposure to light, as with normal use, is acceptable.

Packaging

Packaging
NASONEX is supplied in a single pack (1 bottle) or a dual pack (2 bottles). A sample size is also available.

Not all pack sizes are marketed.

MORE INFORMATION

Drug testing for sports events: This product is a corticosteroid for nasal administration. Although it is not measurable in the blood, corticosteroids may be detected in the urine during drug testing. Thus, prior written permission for its use may be required by sports agencies.

You may want to read this leaflet again. Do not throw it away until you have finished your medication.

Marketing Authorization Holder:
Organon Canada Inc. 16766 route Transcanadienne Kirkland, Quebec H9H 4M7

Manufacturer and Batch Releaser:
Schering-Plough Labo N.V., Industriepark 30, B-2220 Heist-op-den-berg, Belgium

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(THIS IS A MEDICAMENT)
- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children
Council of Arab Health Ministers
Union of Arab Pharmacists