

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH  
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

**The dispensing of this medicine requires a doctor's prescription**

**Read this package insert carefully in its entirety  
before using this medicine**

**The format of this leaflet was determined by  
the Ministry of Health and its content was  
checked and approved in November 2012**

## **Nasonex<sup>®</sup> Nasal Spray**

**Composition:** Each metered actuation delivers:

Mometasone Furoate 50 mcg

**Inactive ingredients:**

Dispersible Cellulose BP 65 cps, Glycerol, Citric acid monohydrate, Sodium citrate dehydrate, Polysorbate 80, Benzalkonium chloride solution, Purified water.

**Therapeutic group:** Topical nasal corticosteroid.

**Therapeutic activity:**

**Nasonex** Spray contains Mometasone Furoate, which is related to the steroid group, and it is intended to treat allergic seasonal or allergic perennial rhinitis in adults and children over 3 years of age.

For the prophylaxis of seasonal allergic rhinitis in adults and children 12 years of age and older, with a known history of seasonal allergic rhinitis - take 2–4 weeks before the start of the pollen season.

**When should the preparation not be used?**

Do not use this medicine if you are sensitive to any of its ingredients.

Do not use if you have a nasal infection, if you have recently been operated on or injured your nose.

**Do not take this medicine without consulting a doctor before starting treatment:**

If you are in your first/third trimester of pregnancy or breastfeeding.

If you are suffering or have suffered in the past from tuberculosis of the respiratory tract.

If you suffer from a fungal, bacterial or viral infection, ocular herpes simplex viral infection, or sores in the nose.

**Warnings:** Inform your doctor if you are pregnant or nursing a baby. Breastfeeding is not recommended during treatment with **Nasonex** Nasal Spray.

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

If you use this preparation over the period of a few months, make sure to have a doctor examine changes in nasal mucosa.

**Drug interactions:** If you are taking another drug concomitantly, including non-prescription medicines and food supplements, especially if you are taking other oral or intravenous steroid medications, or if you have just finished treatment with another medicine, inform the attending doctor in order to prevent hazards or lack of efficacy arising from drug interactions. If you are taking oral or intravenous steroid medications, avoid exposure to chicken pox and measles.

**Side effects:** In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: headache, nasal bleeding, nasal burning, irritation, sneezing, sore throat, or disturbance of taste and smell.

**Side effects that require special attention:**

If you develop an allergic reaction such as onset of wheezing or difficulty breathing shortly after taking the medicine, stop treatment and consult your doctor.

If you develop a nasal and/or pharyngeal fungal infection accompanied by prolonged nasal and/or pharyngeal irritation(rare): stop treatment and consult your doctor.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

**Dosage:** Dosage is according to doctor's instructions only.

**Recommended dosage unless otherwise prescribed by your doctor:**

**Adults and children from 12 years of age:** The standard dose is two sprays in each nostril once a day. When the symptoms are stabilized, the doctor may recommend one spray per nostril once a day.

**Children 3 to 11 years of age:** The standard dose is one spray in each nostril once a day.

Do not exceed the recommended dosage.

This medicine is to be taken at specific time intervals as determined by the attending doctor. If you forgot to take this medicine at the specified time, take a dose as soon as you remember but never take two doses simultaneously!

**Directions for use:** Shake thoroughly. Check the nasal spray for signs of visible deterioration before using.

In order to receive an even dose when spraying, spray 10 times (this primes the pump) before using the spray for the first time. Once a fine spray appears, the pump is ready for use. Do not use the spray after 120 inhalations or after two months of use.

Blow the nose gently. Keeping your head tilted downward, spray the medicine into each nostril in the following manner: while breathing in through the nose, press the pump quickly and firmly. Wait 3-5 minutes; repeat the procedure if necessary.

Rinse the tip of the spray bottle with warm water but make sure that water does not penetrate into the bottle. Wipe with a clean paper towel and close tightly. If the spray pump has not been used for 14 days or longer, prime the pump again by pumping the spray 2 times into the air until a uniform amount of spray is seen coming out with each pump.

To avoid spreading an infection, do not use the same bottle for more than one person.

### **How can you contribute to the success of the treatment?**

Even if there is an improvement in your health, do not discontinue use of this medicine without consulting your doctor.

**Avoid poisoning!** This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

**Do not induce vomiting** unless explicitly instructed to do so by a doctor! This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm. **Do not give this medicine to your relatives, neighbours or acquaintances.**

**Do not take medicines in the dark!** Check the label and the dose each time you take your medicine. Wear glasses if you need them.

**Storage:** Do not freeze. Keep away from heat.

Store in a cool place between temperatures 2°C and 25°C.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine and do not use if the medicine has expired! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medications in the same package.

**License number:** 109.85.29277.00

**Manufacturer:**

Schering-Plough Labo N.V., Heist-Op-Den-Berg, Belgium.

**License holder:** Merck Sharp & Dohme (Israel-1996)  
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