

INSTRUCTIONS FOR USE

NAZOSTER[®] 0.05 % Nasal Spray

Nasal suspension, administered with a metered spray pump

- **Active Substance:** Each spray provides 100 mg suspension, equivalent to 50,00 mcg anhydrous mometasone furoate.
- **Excipients:** Dispersible cellulose 65 cps, glycerine, citric acid monohydrate, sodium citrate dihydrate, polysorbate 80, benzalkonium chloride, phenylethyl alcohol, deionized water.

Please read the USAGE INSTRUCTIONS carefully before starting the use of this pharmaceutical, since it contains important information for you.

- *Keep the usage instructions. You may need to read it again later.*
- *In case you have additional questions, please consult to your physician or your pharmacist.*
- *This pharmaceutical has been personally prescribed for you; do not give it to other persons.*
- *During the use of this pharmaceutical, tell your physician that you are using this pharmaceutical during your visit to the physician or hospital.*
- *Please comply with the instructions herein. Do not use a dose, **lower or higher** than the recommended dose.*

In these Usage Instructions:

1. ***What is NAZOSTER[®] and what is it used for?***
2. ***Issues prior to the use of NAZOSTER[®]***
3. ***How is NAZOSTER[®] used?***
4. ***What are the possible side effects?***
5. ***Storage of NAZOSTER[®]***

are explained.

1. What is NAZOSTER[®] and what is it used for?

NAZOSTER[®], is presented in metered dose packages, comprising 18 g suspension for 140 sprays. It is a white colored aqueous suspension, homogenous on shaking.

NAZOSTER[®] Nasal Spray contains mometasone furoate, included in a drug class called corticosteroids. Mometasone furoate must not be confused with "anabolic steroids," misused by some athletes and administered via tablets and injections. Small quantities of mometasone furoate, when sprayed into the nose, help removing inflammation, itching, congestion and sneezing.

NAZOSTER[®] is used in the treatment of the symptoms of hay fever (also known as seasonal allergic rhinitis) and perennial rhinitis in children of 6 years of age and over and in adults.

NAZOSTER[®] is indicated in the prophylaxis of seasonal allergic rhinitis in adults and in adolescents of 12 years of age and over.

NAZOSTER® may be used in children of 2-6 years of age, diagnosed with allergic rhinitis.

Prophylactic treatment must be initiated 2-4 weeks prior to the expected start of the pollen season.

NAZOSTER® is also used in the treatment of nasal polyps (benign tumor) in adults over 18 years of age.

What are hay fever and perennial rhinitis?

Hay fever, which occurs in certain times of the year, is an allergic reaction, caused by inhalation of tree, grass, weeds pollens and in addition spores of yeast and fungi.

Perennial rhinitis may be caused by hypersensitivity to various substances, such as household dust mites, pet hair flakes, feathers and certain foodstuffs. These allergies cause nasal discharge and sneezing and in connection with swelling in nasal mucosa, cause the feeling of congestion in the nose. NAZOSTER® decreases the swelling and irritation in the nose and therefore removes sneezing, nasal itching, discharge and congestion.

What are nasal polyps?

Nasal polyps are small formations on nasal mucosa and are generally seen in both nostrils. Main symptom is the feeling of congestion in the nose and may affect nasal respiration. Nasal flow, which is felt as a discharge to the back of the throat, loss of taste and smell may be seen. NAZOSTER® decreases inflammation in the nose and allows polyps to gradually contract.

2. Issues prior to the use of NAZOSTER®

DO NOT USE NAZOSTER® in following cases:

If you:

- are allergic (hypersensitive) to mometasone furoate or any components of drug,
- are having a nasal infection, you must wait until the resolution of infection before using nasal spray.
- If you recently have had a nasal surgery or a nasal injury, you must wait for recovery of the injury to your nose before starting to use nasal spray.

USE NAZOSTER® WITH CAUTION in case of following:

If you:

- have previously had tuberculosis or if you have tuberculosis,
- have herpes simplex (virus) infection in your eye,
- have any other infections,
- are taking other corticosteroids orally or via injection,
- have cystic fibrosis.

When using NAZOSTER®, avoid contacting with persons, who have measles or chickenpox. If you come into contact with persons, having these infections, tell your physician.

In case these warnings apply to you, even if for any period in the past, please consult to your physician.

Use of NAZOSTER® with food and beverage

NAZOSTER® may be taken with or without food.

Pregnancy

Please consult your physician or pharmacist before using the pharmaceutical.

If you are pregnant or planning to have a child do not use NAZOSTER[®] unless your physician tells you.

Just like other nasal corticosteroid preparations, when deciding to use NAZOSTER[®] in pregnant women, possible damages on the mother and fetus must be compared with expected benefits.

Consult your physician or your pharmacist immediately in case you realize that you are pregnant during treatment.

Lactation

Please consult your physician or pharmacist before using the pharmaceutical.

If you are lactating or if you are planning to breastfeed your infant, consult your physician before taking NAZOSTER[®]. Just like other nasal corticosteroid preparations, when deciding to use NAZOSTER[®] in lactating women, possible damages on the mother and fetus must be compared with expected benefits.

Driving and Operating Machinery

Effects of NAZOSTER[®] on driving and operating machinery, are not known.

Important information concerning some of the excipients, contained in NAZOSTER[®]:
NAZOSTER[®] contains benzalkonium chloride, which causes irritation in the nose.

Use with other pharmaceuticals

Report all drugs to your physician, including prescription and over-the-counter pharmaceuticals and herbal supplements. Some drugs may alter the mechanism of action of NAZOSTER[®] or NAZOSTER[®] may alter the mechanism of action of other drugs.

If you take oral or injectable corticosteroids for allergy, your physician may recommend to stop these before starting to use NAZOSTER[®]. Some people may experience certain undesired side effects, such as muscle or joint pain, fatigue and depression on discontinuance of oral or injectable corticosteroids. If you experience these symptoms, report to your physician; your physician will make suggestions to you concerning whether you should continue to use nasal spray or not. In addition, you may experience other allergies, such as itching and watering in the eyes, itching or redness on the skin. If you have any of these symptoms and you are concerned, please contact your physician.

In case you are using or have recently used any prescription or over-the-counter pharmaceuticals please report these to your physician or your pharmacist.

3. How is NAZOSTER[®] used?

Always use NAZOSTER[®] as prescribed by your physician. You should check with your physician or your pharmacist in case you are not certain. Do not use the spray for a longer time period or more frequent than prescribed by your physician and do not take higher doses.

Instructions for appropriate usage and dosage/application frequency:

- Hay fever and perennial rhinitis

Adults and children over 12 years of age:

Typical dose in adults and in children over 12 years of age, is two sprays to each nostril once-a-day.

After your symptoms are under control, your physician may recommend you to spray once to each nostril.

You must consult to your physician if you don't start feeling better. Your physician may increase the dose to a maximum of four sprays to each nostrils once-a-day. After your symptoms are under control, your physician may recommend you to decrease the dose to two sprays to each nostril once-a-day.

Children between 2-11 years of age:

Typical dose is one spray per nostril.

Prolonged use of nasal steroids at high doses may cause retardation of growth in children. Your physician may measure the height of your child from time to time during treatment time and may decrease the dose if any effect is seen.

In case your hay fever complaints worsen, your physician may tell you to start using NAZOSTER[®] 2-4 weeks before the start of pollen season; this will help in prevention of emergence of hay fever symptoms. If you have itching or irritation in your eyes, your physician may recommend you to use other treatments, together with NAZOSTER[®]. At the end of the pollen season, your hay fever symptoms may improve and then you may no longer need treatment.

- Nasal polyps

Typical initial dose for adults over 18 years of age, is two sprays to each nostril once-a-day.

In case the symptoms can not be controlled within 5-6 weeks, the dose may be increased to two sprays to each nostril twice-a-day. After the symptoms are taken under control, the physician will request you to decrease the dose to lowest dose, providing symptom control.

In case no improvement is seen within 5-6 weeks with twice-a-day administration you must consult your physician to discuss other treatments to replace NAZOSTER[®].

Administration route and method:

Preparation of Nasal Spray for use:

In NAZOSTER[®] Nasal Spray, there is a protective cover, protecting nose and keeping it clean. Before using the spray, remove this cover and reattach after use.

Do not puncture the tip of the spray pump.



In the first use, in order to adjust spray pump, the drug must generally be sprayed 10 times, until it is seen that it is sprayed regularly.

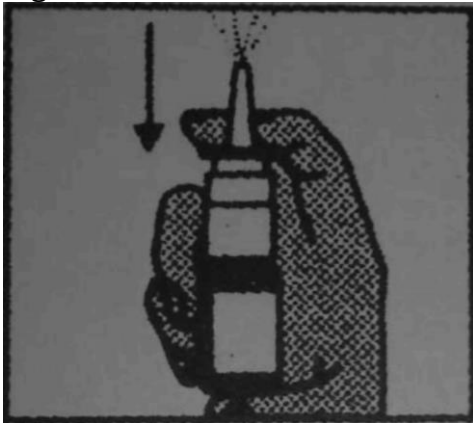
1. It must be shaken well before each use.
2. Put your index finger and middle finger to each two sides of nose and place your thumb under the bottle.
3. Move the bottle away from your nose, and spray by pressing with your fingers.

In case spray pump is not used for a term of 14 days and over, in order to adjust spray pump before use, the drug must be sprayed generally twice until a regular spray is seen.

Usage instructions

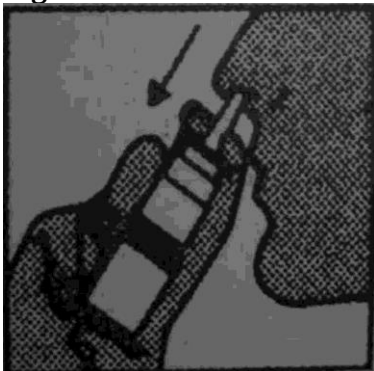
1. Shake bottle gently and remove protective cap (Figure 1).

Figure 1



2. Clear your nose slowly.
3. By closing one of your nostrils, place the tip of the spray pump to other nostril (Figure 2). While slightly bowing your head, keep the bottle straight.

Figure 2



4. Start breathing with your nose and when inhaling, press ONCE with your finger and spray to your nose.
5. Exhale from your mouth. Repeat the procedure at step 4 once more to the same nostril.
6. Move bottle away from your nostril and exhale from your mouth.
7. For other nostril, repeat procedures from step 3 to step 6.

After using the spray, wipe with a clean napkin or tissue and put the cover back.

Cleaning of Nasal Spray

It is important to clean your Nasal spray regularly, otherwise it will not spray properly. Remove the protective cover and open the spray pump. Wash spray pump and protective cover in hot water and dry. Do not try to puncture the tip of the spray pump with a needle or a sharp object; because this will damage the pump and will prevent you from getting correct pharmaceutical dose. Leave to dry at a warm place. Push spray into the bottle and place the protective cover. After cleaning the spray, when using for the first time, it must be sprayed twice until regular spray is observed.

Different age groups:

Use in children: In the children, an adult must assist in the use this drug.

Use in elderly: There are no special use conditions.

Special usage conditions:

Kidney/liver failure: There is no data concerning use in patients with kidney or liver failure.

In case you have an impression that NAZOSTER[®] is too weak or too strong, talk to your physician or your pharmacist.

If you used more NAZOSTER[®] than you should have used

In case you used NAZOSTER[®] at an amount that is more than you were supposed to, talk to a physician or a pharmacist.

If you use steroids for a long time and at high doses, rarely they may affect some of your hormones. May retard growth and development in children.

If you forget to use NAZOSTER[®]:

Try to take your drug as recommended.

When you forget to take nasal spray at the right time, take it when you remember and then continue normal use.

Do not take double doses to compensate for forgotten doses.

Effects, which may occur on termination of treatment with NAZOSTER[®]

In some patients NAZOSTER[®] starts to relieve symptoms 12 hours after the first dose; yet no benefits may be seen from treatment for up to two days. It is very important to use your nasal spray regularly. Do not discontinue your treatment unless you are told by your physician even if you feel good.

If you have any further questions concerning this product, ask your physician or pharmacist.

4. What are the possible side effects?

Like all pharmaceuticals, side effects can be seen in people that are sensitive to the contents of NAZOSTER®.

If any of the following occurs, stop taking NAZOSTER® and inform your doctor IMMEDIATELY and refer to the emergency service of the nearest hospital.

Rare: Hypersensitivity reaction (such as bronchospasm (spasm in bronchi), dyspnea (shortness of breath)) following intranasal administration may be seen.

Very rare: Anaphylaxis (hypersensitivity reaction) and angioedema (itchy condition on skin) have been reported.

All these are serious side effects.

In case you have one of these, it means that you have a serious allergy to NAZOSTER®. You may need emergency medical attention or hospitalization.

Other side effects:

The side effects have been described as shown in the following categories:

Very common: Seen in at least 1 of 10 patients.

Common: May be seen in less than one out of 10 patients yet more than one out of 100 patients.

Uncommon: May be seen in less than one out of 100 patients yet more than one out of 1000 patients.

Rare: May be seen in less than one out of 1,000 patients yet more than one out of 10,000 patients.

Very rare: May be seen in less than one out of 10,000 patients.

Unknown: Can not be estimated from available data.

- Undesired treatment related events, reported in adult and adolescent patients with allergic rhinitis, are given below:

Common: Epistaxis (nasal bleeding), pharyngitis (sore throat), nasal (nose) burning sensation, nasal irritation, nasal ulceration, sneezing, headache

Unknown: In children, retardation in growth rate in case of prolonged use, vision disorders in connection with increase in eye pressure (glaucoma).

It is recommended to monitor the heights of children, receiving prolonged treatment with nasal corticosteroids.

Epistaxis (nasal bleeding) is generally mild and resolve spontaneously. Although incidence (frequency) is higher (5 %) compared to placebo (drug without active ingredient) it is comparable to active control nasal corticosteroids (up to 15 %), subject to comparison and it is lower. The incidence of all other effects are comparable to placebo.

In pediatric patients, side effect incidence, for example, headache (3 %), epistaxis (6 %), nasal irritation (2 %) and sneezing (2 %) are comparable to placebo.

- Nasal polyps (benign tumor): In patients, treated for nasal polyps, the frequency of undesired events is comparable to placebo and is similar to that, seen in patients with allergic rhinitis. In

clinical studies for polyps, undesired treatment-related events, reported in 1 % or more of patients, are as follows:

Very common: Nose bleeding, very common with 200 micrograms twice a day.

Common: Upper respiratory tract infection common with once-a-day 200 micrograms, nose bleeding common with once-a-day 200 micrograms, throat irritation common with twice-a-day 200 micrograms, headache common with once-a-day 200 micrograms and twice-a-day 200 micrograms.

Uncommon: Upper respiratory tract infection, uncommon with twice-a-day 200 micrograms

Very rarely, taste and smell disorders have been reported.

Following the use of intranasal corticosteroids, rarely nasal septum perforation (penetration of nasal cartilage) or cases of increase in intraocular pressure and/or cataract, have been reported.

The effects of nasal corticosteroids on entire body, may be particularly apparent when prescribed at high doses in particular for long times.

In case you observe any side effects, which are not mentioned in these usage instructions, please inform your physician or your pharmacist.

Reporting of side effects

In case of a side effect, which is given in the Usage Instructions or not, consult your physician, pharmacist or nurse. In addition, report your side effects to Turkey Pharmacovigilance Center (TÜFAM) by clicking on "Pharmaceutical Side Effect Report" button on www.titck.gov.tr via side effect report line 0 800 314 00 08. By reporting side effects, you will provide a contribution to obtain greater information concerning safety of the pharmaceutical you use.

5. Storage of NAZOSTER®

Keep NAZOSTER® away from reach and sight of children and in package.

Keep at room temperature below 25°C. Do not freeze.

Use in compliance with expiry date.

Do not use NAZOSTER® after the expiry date on the package.

In case you notice irregularities on the product and/or package, do not use NAZOSTER®.

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This Instructions for Use document has been approved on 14/01/2014.