

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

The medicine is dispensed without a doctor's prescription

Steronase AQ

Nasal Spray

Triamcinolone Acetonide

Active ingredient: Each actuation releases: Triamcinolone Acetonide 55 mcg

Inactive ingredients: See section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine.

If you have further questions, refer to the doctor or pharmacist.

The medicine is sold without a doctor's prescription; however, you must use it carefully to get the best results from it. Use the preparation according to the instructions in the "How should you use the medicine" section in this leaflet. Consult the pharmacist if you need further information. Refer to a doctor if the symptoms worsen or do not improve within 14 days.

Keep this leaflet; you may need to read it again.

This medicine is intended for adults and children over 2 years of age. Use in children and adolescents under 18 years of age is by a doctor's prescription.

1. WHAT IS THE MEDICINE INTENDED FOR?

Treatment of seasonal and perennial allergic rhinitis symptoms in adults and children over 2 years of age.

Therapeutic group: corticosteroid for topical administration in the nose.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

You are sensitive (allergic) to triamcinolone acetonide or to any of the other ingredients of this medicine (see section 6). Symptoms of an allergic reaction to Steronase AQ Nasal Spray include: a rash, itching, swallowing or breathing difficulties, swelling of the lips, face, throat or tongue.

Special warnings regarding use of the medicine:

Before treatment with the medicine, tell the doctor if:

- You have any untreated infection of the nose or throat. If you get a fungal infection while using Steronase AQ Nasal Spray, stop using the spray until treatment of the infection has been completed.
- You have recently had a nose operation, or had an injury or ulcer in the nose.
- You are being transferred to using Steronase AQ Nasal Spray after using medicines or injections that contain steroids.
- You have had glaucoma or cataract.

Refer to your doctor if you experience blurred vision or other visual disturbances.

If you are not sure if the above applies to you, consult the doctor or pharmacist before using this medicine.

Children and adolescents

The medicine is not intended for children under 2 years of age. Use in children and adolescents under 18 years of age is by a doctor's prescription.

Operations or periods of stress:

Your doctor may recommend a higher than normal dose of this medicine for you, as per medical considerations. If your dose is increased, tell the doctor if you are going to have an operation or are feeling unwell. This is because a higher than normal dose of this medicine can lower the ability of your body to heal or cope with stressful situations. If this happens, your doctor may decide that you need further treatment with another medicine.

Drug interactions:

If you are taking, or have recently taken, or plan to take, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because Steronase AQ Nasal Spray can affect the way some other medicines work and some medicines can affect the way Steronase AQ Nasal Spray works. Certain medicines may increase the effect of Steronase AQ Nasal Spray and your doctor may wish to monitor you carefully if you are taking these medicines (including certain medicines for HIV: ritonavir and cobicistat).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning a pregnancy, do not use this medicine, unless your doctor has advised you and decided that the benefits of using this medicine are higher than the possible risk to your baby.

Driving and using machines

There are no known effects of Steronase AQ Nasal Spray on the ability to drive or use machines.

Important information about some of the ingredients of the medicine:

Steronase AQ Nasal Spray contains benzalkonium chloride – 15 mcg per actuation. Benzalkonium chloride may cause irritation or swelling inside the nose, especially with prolonged use.

3. HOW SHOULD YOU USE THE MEDICINE?

For use in the nose only.

Always use according to the doctor's or pharmacist's instructions. Consult with the doctor or pharmacist if you are not sure about the dosage or treatment regimen of the medicine. This medicine only works if used regularly. It may take 3-4 days before you notice an improvement of the symptoms.

The usual dosage is generally:

Adults over 18 years of age:

- 2 actuations in each nostril, while gently inhaling, once a day.
- Once the symptoms of allergy are improved, lower the dosage to 1 actuation in each nostril, once a day.
- If the symptoms do not go away within 14 days, refer to a doctor or pharmacist.
- Do not use the medicine every day for longer than 3 months without consulting your doctor.

Children from the age of 2 to 18: By a doctor's prescription.

- Administration of the medicine should be under an adult's supervision.

Do not use Steronase AQ Nasal Spray for more than 3 months in children under 12 years old.

Do not give to children and adolescents under 18 years of age without being instructed to do so by a doctor.

Do not exceed the recommended dose

How to use the spray

Before using the nasal spray, blow your nose gently to clean the nostrils.

1. Preparing the bottle.

- Remove the purple cap by pulling upwards
- Shake the bottle gently before use

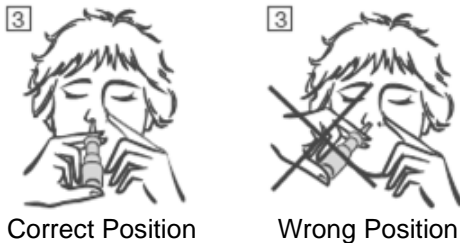
2. If you are using the spray for the first time.

- Hold the bottle upright
- Point the spray away from you while doing this
- Fill the pump with spray by pressing the spray nozzle downwards. This is called priming.
- Press and release 5 times
- Do this until a fine spray is produced
- The spray is now ready for use.



3. Using the spray

- Close one nostril with your finger
- Hold the bottle upright and insert the spray nozzle into the other nostril, to a depth that is comfortable for you



- Breathe in through the nose, while your mouth is closed
 - While you are doing this, press the spray nozzle to release one spray
4. Then, breathe out through the mouth
5. **Repeat** steps 3 and 4 if you have to spray again in the same nostril or in the other nostril.
6. **After using the spray**
- To keep the spray nozzle clean, wipe it gently with a clean cloth (tissue) or handkerchief after each use.
 - Replace the cap over the spray nozzle

If the preparation has not been used for more than two weeks:

- Prime it again to fill the spray nozzle.
- When doing so, hold the bottle so that the spray nozzle is pointing away from you
- To prime, spray once in the air before use
- Always shake the bottle gently before use

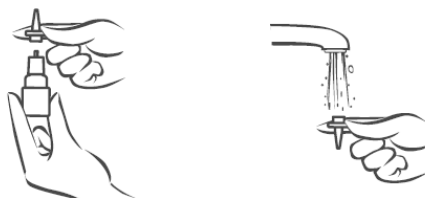
Cleaning the spray

- If the spray does not work, its nozzle may be blocked. **Never** try to unlock the blockage or enlarge the hole at the end of the spray nozzle with a pin or other sharp object, as this can stop the spray from working.

Clean the nasal spray at least once a week.
If its nozzle gets blocked, clean it more often.

Instructions for cleaning the spray:

1. Remove the cap
2. Gently pull off the spray nozzle only
3. Soak the cap and spray nozzle in warm water for a few minutes
4. Rinse under cold running tap water
5. Shake off any water that is left
6. Allow the parts to dry in the air.
7. Re-fit the spray nozzle.
8. Prime the spray until a uniform mist is formed
9. Use as normal.



If you accidentally used a higher dosage of Steronase AQ Nasal Spray

It is important to take the medicine as per the dosage indicated on the pharmacist label or as advised by the doctor. Adhere to the dosage recommended for you; a lower or higher dosage may worsen your symptoms.

The likelihood that an overdose will cause problems is low, but if the entire contents of the bottle are taken by mouth, you may experience intestinal or abdominal pain and discomfort. Refer to a doctor if you used more Steronase AQ Nasal Spray than you should.

If you forget to use Steronase AQ Nasal Spray:

If you forgot to use this spray at the required time, use it as soon as you remember. Do not take a double dose to make up for a forgotten dose. **Take the next dose at the usual time and consult a doctor. Adhere to the treatment regimen as recommended by the doctor.**

If you stop using Steronase AQ Nasal Spray:

If you stop using the medicine, your symptoms may return within a few days.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

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

4. SIDE EFFECTS

As with any medicine, use of Steronase AQ Nasal Spray may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop using Steronase AQ Nasal Spray and immediately refer to a doctor or proceed to a hospital if:

You have an allergic reaction to Steronase AQ Nasal Spray. The signs (frequency not known) may include: a rash, itching, swallowing or breathing difficulties, swelling of the lips, face, throat or tongue.

Common side effects (occur in 1-10 in 100 users):

- Runny nose, headache, sore throat and/or cough
- Nosebleed
- Inflammation/irritation of the airways (bronchitis)
- Heartburn or indigestion
- Flu-like symptoms (fever, muscle pain, weakness and/or fatigue)
- Problems with teeth

Other side effects (frequency not known: cannot be determined from the available data):

- Irritation and dryness inside the nose
- Congested or blocked sinuses
- Sneezing
- Changes in taste and smell
- Feeling sick (nausea)
- Sleeping problems, dizziness, tiredness
- Shortness of breath
- A decrease in blood cortisol level (lab value)
- Cloudiness of the lens in the eye (cataract), elevated pressure inside the eyeball (glaucoma)
- Blurred vision

In some people, Steronase AQ Nasal Spray can cause damage to the middle part in the nose (nasal septum). Discuss any worries you may have about this with the doctor or pharmacist.

Additional side effects in children

If your child is using this medicine, it may disrupt his growth rate. The doctor will have to regularly check your child height and lower the dosage if necessary. In addition, the doctor may consider referring the child to a pediatric specialist.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, refer to the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without being explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Do not store above 25°C.

After first opening, use Steronase AQ Nasal Spray within two months.

Do not dispose of any medicine via waste water or the household waste.

Ask your pharmacist how to dispose of medicines that you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Glucose anhydrous, microcrystalline cellulose and carboxymethylcellulose sodium, benzalkonium chloride (15 micrograms/delivered dose), disodium edetate, polysorbate 80, purified water, hydrochloric acid and sodium hydroxide (for pH adjustment).

What the medicine looks like and the contents of the package

Steronase AQ Nasal Spray is a suspension to be sprayed into the nose. The spray comes in a white plastic bottle, with a pump and with a nozzle at the tip of the bottle. The bottle has a cap, which keeps the nozzle clean and prevents accidental spraying.

The bottle contains 120 metered doses.

Registration holder and importer and address: Pharmashalom Ltd., 21 Ha'Melacha St., Rosh-Ha'Ayin 4809157.

This leaflet does not contain all of the information about the preparation. If you have any question or are unsure about something, please refer to a doctor.

Registration number in the National Drug Registry of the Ministry of Health: 691228059.

Revised in October 2022 according to MOH guidelines.