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Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed without a doctor's prescription

Steronase AQ Nasal Spray

Suspension

Active ingredient

triamcinolone acetonide 0.055% w/w

Each actuation releases 55 mcg triamcinolone acetonide.

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Use the preparation according to the instructions in the section about dosage in this leaflet. Consult the pharmacist if you need further information. Consult your doctor if the symptoms of illness get worse or do not improve within 14 days.

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 THIS 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.

Nasal symptoms of allergy include sneezing, itching, blocked, stuffy or runny nose. These can be caused by:

- Animal fur or house dust mites. This type of allergy can happen at any time of the year and is called 'perennial allergic rhinitis'.
- Pollen. This type of allergy, such as hay fever, can be caused by different pollens in different seasons of the year and is called 'seasonal allergic rhinitis'.

This medicine only works if taken on a regular basis and may not help the symptoms straight away. It helps some people within the first day of treatment, and for other people it may take 3 to 4 days to feel a relief.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

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

Before treatment with the medicine, tell your 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 have been transferred to using Steronase AQ Nasal Spray after using injections or tablets that contain steroids.

- You have ever had glaucoma or cataract.

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

Systemic effects

When corticosteroids, including triamcinolone acetonide, are taken for long periods of time or at high doses for long periods of time, side effects may occur due to absorption of the medicine in the body (e.g. the normal production of steroidal hormones can be affected). These side effects are much less likely to occur with corticosteroid nasal sprays than with corticosteroids taken orally (e.g. tablets). Contact your doctor if you experience any side effect. See also section 4 'Side effects'.

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 the body to heal or cope with stress. If this happens, your doctor may decide that you need further treatment with another 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.

Interactions with other medicines

If you are taking, or have recently taken, or might take, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

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, consult your doctor or pharmacist before using this medicine.

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 this medicine's ingredients

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

3. HOW TO USE THIS MEDICINE?

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

For use in the nose only.

The recommended dosage is usually:

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, contact 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.

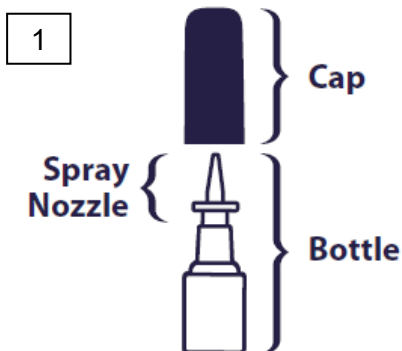
Do not exceed the recommended dose.

How to use the spray

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

1. Preparing the bottle

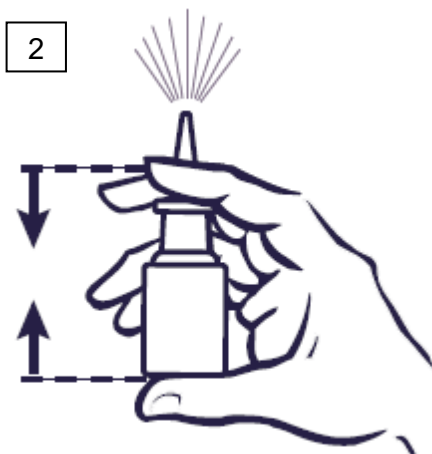
- Remove the purple cap by pulling upwards



- Shake the bottle gently before use

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

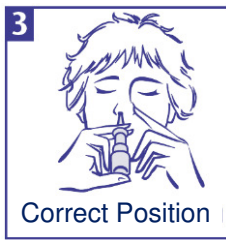
- Hold the bottle upright
- Point the spray away from you while holding the bottle
- Fill the pump with spray by pressing the spray nozzle downwards. This is called priming
- Press and release 5 times
- Do this until a fine spray is produced
- The spray is now ready for use.



3. Using the spray

- Close one nostril with the finger
- Hold the bottle upright and insert the spray nozzle into the other nostril as deep as is comfortable for you

- Breathe in through the nose, while the 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

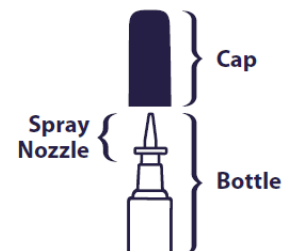
- If the spray does not work, its nozzle may be blocked. **Never** try to open the blockage or enlarge the hole at the end of the spray nozzle with a pin or other sharp object, as this will destroy the spraying mechanism.



Clean the nasal spray at least once a week.
If its nozzle gets blocked, you can 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 fine mist is formed
9. Use as normal



If you have accidentally used a higher dosage

It is important to take the medicine as per the dosage indicated on the pharmacist's 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 abdominal or intestinal discomfort. Contact a doctor if you used more Steronase AQ Nasal Spray than you should.

If you forget to use the medicine

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.

If you stop using the medicine

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

If you experience any side effects (withdrawal symptoms) following sudden discontinuation after prolonged use, contact your doctor. See section 4 'Side effects' for more information.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Steronase AQ Nasal Spray may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using Steronase AQ Nasal Spray and immediately contact 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 rash, itching, swallowing or breathing difficulties, swelling of the lips, face, throat or tongue.

Common side effects - affect 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

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- Irritation and dryness inside the nose
- Congested or blocked sinuses
- Sneezing
- Changes in taste and smell
- 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 intra-ocular pressure (glaucoma)
- Blurred vision
- Sudden discontinuation of corticosteroids after prolonged use may result in withdrawal symptoms like joint pain, muscle pain, shaking, weight loss, anxiety, nasal drip and bleeding from the nose. However, these symptoms are extremely rare for corticosteroid nasal spray as compared to corticosteroids taken orally (e.g. tablets).

In some people, Steronase AQ Nasal Spray may cause damage to the middle part of the inside of 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's height and lower the dosage if necessary. In addition, the doctor may consider referring the child to a pediatric specialist.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link:

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

5. HOW TO STORE THE MEDICINE?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

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

Storage conditions: Do not store above 25°C.

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

Do not discard the medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

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

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

What the medicine looks like and the contents of the pack:

A suspension to be sprayed into the nose. The suspension 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's and importer's name and address: Pharmashalom Ltd., 21 Ha'Melacha St., Rosh-Ha'Ayin 4809157.

Registration number in the Ministry of Health National Drug Registry: 069-12-28059-00

Revised in August 2023 according to Ministry of Health guidelines.