

Patients should use NASACORT AQ Nasal Spray on a regular once-daily basis for optimal effect. It is also important to shake the bottle well before each use. Do not blow your nose for 15 minutes after using the spray. NASACORT AQ Nasal Spray, like other corticosteroids, does not have an immediate effect on rhinitis symptoms. Although improvement in some patient symptoms may be seen within the first day of treatment, maximum benefit may not be reached for up to one week. The patient should not increase the prescribed dosage but should contact the physician if symptoms do not improve or if the condition worsens.

17.5 Keep Spray Out of Eyes

Patients should be informed to avoid spraying NASACORT AQ Nasal Spray in their eyes.

17.6 Patient Package Information

IMPORTANT: Please read these instructions carefully before using your NASACORT® AQ Nasal Spray

Nasacort® AQ (triamcinolone acetonide)

[na' za-cort]

Nasal Spray

Patient Information:

These instructions provide important information about Nasacort AQ. Ask your healthcare provider or pharmacist if you have any questions.

Important: For use as a nasal spray only.

What is Nasacort AQ?

Nasacort® AQ Nasal Spray is a prescription medicine called a corticosteroid used to treat nasal symptoms of seasonal and year around allergies in adults and children 2 years of age and older. When Nasacort AQ is sprayed in your nose, this medicine helps to lessen the symptoms of sneezing, runny nose, nasal itching and stuffy nose.

Nasacort is not for children under the age of 2 years.

Who should use Nasacort AQ?

Do not use Nasacort AQ if you have had a reaction to triamcinolone acetonide or to any of the other ingredients in Nasacort AQ. See the end of this leaflet for a complete list of ingredients in Nasacort AQ.

What should I tell my healthcare provider before using Nasacort AQ?

Tell your healthcare provider if you are:

- pregnant or planning to become pregnant

- breastfeeding
- exposed to chickenpox or measles
- feeling unwell or have any symptoms that you do not understand

Tell your healthcare provider about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

How do I use Nasacort AQ?

- Use Nasacort AQ exactly as your healthcare provider tells you.
- You will get the best results if you use Nasacort AQ regularly and without missing a dose. Do not take extra doses.
- Nasacort AQ should be used as a nasal spray only. Do not spray it in your eyes or mouth.
- Your healthcare provider will tell you how and when to use Nasacort AQ. Do not use more Nasacort AQ or take it more often than your healthcare provider tells you.
- The prescription label will usually tell you how many sprays to take and how often. If it does not or if you are unsure, ask your healthcare provider or pharmacist.
 - **For people aged 12 years and older**, the usual dose is **2 sprays in each nostril, one time each day**.
 - **For children aged 6 to 12 years**, the usual dose is **1 spray in each nostril, one time each day**. Your healthcare provider may tell you to take 2 sprays in each nostril **one time each day**.
 - **For children aged 2 to 5 years**, the usual dose is **1 spray in each nostril, one time each day**.
 - **An adult should help a young child use this medicine.**

Do not stop taking Nasacort AQ without telling your healthcare provider. Before you throw away Nasacort AQ, talk to your healthcare provider to see if you need another prescription. If your healthcare provider tells you to continue using Nasacort AQ, throw away the empty or expired bottle and use a new bottle of Nasacort AQ.

- For detailed instructions, see the “Patient Instructions for Use” at the end of this leaflet.
- Some symptoms may get better on the first day of treatment. It generally takes one week of use to feel the most benefit.
- Protect your eyes from the spray. If you get the spray in your eyes, rinse your eyes well with water.
- If your symptoms do not improve, or if they become worse, contact your healthcare provider.

- Tell your healthcare provider if you have irritation, burning or stinging inside your nose that does not go away when using Nasacort AQ.

What are the possible side effects of Nasacort AQ?

Common side effects of Nasacort AQ include:

Sore throat, headache, and nosebleeds. If you have an increase in nosebleeds after using Nasacort AQ or the inside of your nose hurts, contact your healthcare provider.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Patient Instructions for Use

Read these instructions carefully before using your Nasacort AQ.

Before using the spray pump bottle:

1 Pull the blue cover and the clip off the spray pump unit. See figure A.

If the top part of the spray pump comes off of the bottle when removing the cover, then re-insert the stem back into the pump.



Figure A.

2. Shake the spray pump bottle before each use.

Priming the Spray Pump Bottle

3. Before using the spray pump bottle for the first time, it must be primed. To prime, put your thumb on the bottom of the bottle and your index and middle fingers on the “shoulders” of the bottle, and hold it upright. See figure B.



Figure B

4 Point the bottle away from your eyes. Push the bottle up with your thumb and against your two fingers **firmly** and **quickly** until a fine spray appears. Do this pumping action 5 times. Now your spray pump bottle is primed and ready for use. A fine mist can only be made by a rapid and firm pumping action.

5 Repeat priming the pump, if it has not been used for more than 2 weeks. To reprime, shake the spray pump bottle and pump it just one time. Now the spray pump bottle is reprimed.

Using the spray:

6. Gently blow your nose to clear it, if needed. For small children, be sure to help them gently blow their nose, as much as possible.
7. Pull off the blue cover and clip as shown in figure C. Shake the spray pump well.



Figure C

8. Hold the spray pump firmly, with the index and middle finger on either side of the spray tip. Place your thumb on the bottom of the bottle. **Be careful** so that your fingers will not slip off the spray pump as you spray inside your nose. See figure D.



Figure D

9. Put the spray tip into one side of your nose. The tip should not reach far into the nose. Rest the side of your index finger against your upper lip. Tip your head back a little and aim the spray toward the back of your nose. See figure E.



Figure E

10. Press against the other side of your nose with your finger so the nostril is closed. Pump the spray bottle by pushing on the bottom of the bottle with your thumb **firmly** and **quickly** for the full dose of medicine. Sniff gently at the same time to help the medicine get to the back of your nose. See figure F. Repeat this step for the other side.



Figure F

11. Repeat steps 8, 9 and 10 if your healthcare provider tells you to use more than one spray in each nostril.
12. Do not blow your nose for 15 minutes after using the spray.
13. After use, wipe the nozzle on the spray bottle with a clean tissue, and replace the blue cover.
14. Keep the cover and the clip on the spray pump bottle when not in use.

Cleaning the spray pump bottle:

15. To clean the spray pump bottle, remove the blue cover and the spray nozzle only. Soak the cover and spray nozzle in warm water for a few minutes, and then rinse under cold water. See figure G.



Figure G

16. Shake or tap off the excess water and allow to air dry. Once the cap and spray nozzle are dry, put the nozzle back onto the bottle, and prime the bottle as necessary until a fine mist is made. Use the spray as directed by your healthcare provider.

If the spray bottle does not work:

The hole in the tip of the nozzle may be blocked. Never try to unblock the spray hole or enlarge it with a pin or other sharp object. This will make the spray mechanism not work correctly. Changing the size of the opening can change the amount of medicine you or your child will receive. This could cause an overdose of the medicine. To clean nasal spray pump bottle, refer to Step 15.

Important information

Repriming the spray pump is only necessary when it has not been used for more than 2 weeks. To reprime, shake the bottle and only pump the spray bottle one time. Do not reprime if you use the spray more often than every two weeks.

Each Nasacort AQ bottle contains 120 doses of medicine plus a little extra for priming the pump. A check-off chart is included with your Nasacort AQ to help you keep track of the number of sprays. This will help make sure that you receive 120 sprays of Nasacort AQ.

Nasacort® AQ 120 Spray Check-Off

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
17	18	19	20	21	22	23	24
25	26	27	28	29	30	31	32
33	34	35	36	37	38	39	40
41	42	43	44	45	46	47	48
49	50	51	52	53	54	55	56
57	58	59	60	61	62	63	64
65	66	67	68	69	70	71	72
73	74	75	76	77	78	79	80
81	82	83	84	85	86	87	88
89	90	91	92	93	94	95	96
97	98	99	100	101	102	103	104
105	106	107	108	109	110	111	112
113	114	115	116	117	118	119	120

- Keep this chart near your Nasacort AQ.
- Check off one circle each time you use this bottle of Nasacort AQ.
- When you reach 120 sprays, throw the bottle away.
- If you use more than 120 sprays, you will not get the right amount of medicine.

How should I store Nasacort AQ?

- Store Nasacort AQ between 68° to 77°F (20° to 25° C).
- After using 120 sprays, throw the medicine away, as directed by your healthcare provider, even if the bottle is not empty. You may not get enough medicine if you use the bottle after 120 sprays.

Keep Nasacort and all medicines out of the reach of children. General information about the safe and effective use of Nasacort AQ.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information. Do not use Nasacort AQ for a condition for which it was not prescribed. Do not give Nasacort AQ to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about Nasacort AQ. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Nasacort AQ that is written for health professionals.

For more information, go to www.NasacortAQ.com or call 1-800-XXX-XXXX.

What are the ingredients in Nasacort AQ?

Active ingredient: triamcinolone acetonide

Inactive ingredients: Microcrystalline cellulose, carboxymethylcellulose sodium, polysorbate 80, dextrose, benzalkonium chloride, and edetate disodium are contained in this aqueous medium; hydrochloric acid or sodium hydroxide may be added to adjust the pH to a target of 5.0 within a range of 4.5 and 6.0.

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