

Nasacort 55 micrograms/dose, nasal spray suspension

Triamcinolone acetonide sanoofi aventis

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Nasacort is and what it is used for
2. Before you use Nasacort
3. How to use Nasacort
4. Possible side effects
5. How to store
6. Further information

1. What Nasacort is and what it is used for

Pharmacotherapeutic group

Nasacort contains a medicine called triamcinolone acetonide. This belongs to a group of medicines called corticosteroids which means it is a type of steroid. It is given to treat the nasal symptoms of allergic rhinitis.

Therapeutic indications

Nasal symptoms of allergy include sneezing, itching, and having a blocked, stuffy or runny nose. These can be caused by things such as:

- 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. This is called 'seasonal allergic rhinitis'.

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

2. Before you use Nasacort

Contraindications

Do not use Nasacort if:

- You are allergic (hypersensitive) to triamcinolone

acetonide or any of the other ingredients of Nasacort (see Section 6 : Further Information)

Signs of an allergic reaction to Nasacort include: a rash (hives), itching, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Appropriate precautions for use: special warnings Take special care with Nasacort

Check with your doctor or pharmacist before using your medicine if:

- You have any infection of the nose or throat that is not treated. If you get a fungal infection while using Nasacort, stop using the spray until the infection has been treated.
 - You have recently had a nose operation, or had an injury or ulcer in the nose.
 - You are being transferred from steroid injections or tablets to Nasacort Spray.
 - You have had glaucoma or cataracts
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Operations or times of stress

Your doctor may advise you to take a higher than normal dose of this medicine for medical reasons. If your dose is increased, tell your doctor if you are going to have an operation or are feeling unwell. This is because higher than normal doses of this medicine can lower your body's ability to heal or cope with stress. If this happens, your doctor may decide you need further treatment with another medicine to help.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription. This is because Nasacort can affect the way some other medicines work. Also some medicines can affect the way Nasacort works.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding you should not use this medicine unless your doctor has advised you that the benefits of using it are higher than the possible risk to your baby.

Driving and using machines

Nasacort has no known effect on your ability to drive or use tools or machines.

Important information about some of the ingredients of Nasacort

Nasacort contains benzalkonium chloride which is an irritant and may cause skin reactions.

3. How to use Nasacort

Always use Nasacort exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The medicine only works if it is used regularly. It can take 3 to 4 days before you notice your symptoms getting better.

How much Nasacort to use

Adults and children (over 12 years)

- The usual starting dose is 2 sprays in each nostril each day
- Once the symptoms of allergy are under control, the dose may be lowered to 1 spray in each nostril each day

Children (6 to 12 years)

- The usual dose is 1 spray in each nostril each day
- If the symptoms do not go away, then the dose may be increased to 2 sprays in each nostril each day
- The dose can then be lowered again to 1 spray in each nostril each day
- Do not use Nasacort for more than 3 months in children under 12 years old

Children (under 6 years)

- Check with your doctor or pharmacist before using

How to use the spray

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

1. Preparing the bottle

- Remove the blue cover by pulling upwards.
- Pull off the blue plastic cap.
- 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 nozzle downwards. This is called priming.
- Press and release it 5 times
- Do this until a fine spray is produced
- The spray is now ready to use.

3. Using the spray

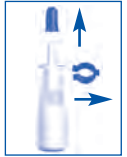
- Close one nostril with your finger
- Hold the bottle upright and put the nozzle into the other nostril as far as is comfortable
- Breathe in gently through your nose with your mouth closed
- While you are doing this, press the nozzle to deliver one spray

4. Then breath out through your mouth

5. Repeat steps 3 and 4 if you have to spray again in the same nostril and for the other nostril

6. After using the spray

- To keep the spray nozzle clean, wipe it carefully with a clean tissue or handkerchief after each use



- Press the blue plastic clip back into place to stop accidental release of the spray
- Replace the blue cover over the nozzle

If the nasal spray has not been used for more than 2 weeks:

- It needs to be primed again, to fill the nozzle with the spray
- The nozzle should be pointed away from you while you are doing this
- To prime, spray into the air once before use
- Always shake the bottle gently before use

Cleaning the spray

If the spray does not work, the nozzle may be blocked.

Never try to unblock it or enlarge the tiny spray hole with a pin or other sharp objects. This is because it can stop the spray from working.

The nasal spray should be cleaned at least once a week. It can be cleaned more often if it gets blocked.

Instructions for cleaning the spray:

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



If you use more Nasacort than you should

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse. An overdose is unlikely to cause problems, however, if you have taken the entire contents of the bottle by mouth you may have stomach or gut discomfort. Talk to a doctor if you use more Nasacort than you should.

If you forget to use Nasacort

If you have forgotten to use Nasacort, use it as soon as you remember. Do not use a double dose to make up for a forgotten dose.

If you stop using Nasacort

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Nasacort can cause side effects, although not everybody gets them.

Stop using Nasacort and see a doctor or go to a hospital straight away if:

- you have an allergic reaction to Nasacort. The signs (frequency not known) may include: a rash (hives), itching, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Tell your doctor or pharmacist if you have any of the following side effects. Also tell them if you notice any side effects not listed in this leaflet.

Common side effects (affects 1 to 10 users in 100)

- runny nose, headache, sore throat and/or cough,
- nosebleeds,
- 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)

- irritation and dryness on the inside of your nose,
- sinuses become congested or blocked,
- sneezing,
- changes in the way things taste or smell,
- feeling sick (nausea),
- sleeping problems, feeling dizzy or tired,
- shortness of breath (dyspnoea),
- a decrease in the levels of cortisol in the blood (lab value),
- cloudiness of the lens in the eye (cataract), elevated pressure inside the eyeball (glaucoma).

In some people, Nasacort can cause damage to the middle part of the inside of the nose (called 'nasal septum'). Discuss any worries you may have about this with your doctor or pharmacist.

Information for Children

If your child has been using this medicine for a long time, it can affect how fast they grow. This means that your doctor will need to regularly check their height. If their growth rate is affected your doctor may lower the dose. In addition, your doctor may consider referring your child to a paediatric specialist.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Nasacort

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use Nasacort after the expiry date. This is marked on the carton and the bottle after "EXP". The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Following the first opening Nasacort should be used

within 1 month for the 30 spray pack or 2 months for the 120 spray pack.

- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Nasacort contains

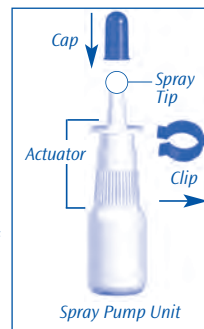
The active substance is triamcinolone acetonide. Each spray delivers 55 micrograms triamcinolone acetonide.

The other ingredients are:

- microcrystalline cellulose,
- carmellose sodium,
- polysorbate 80,
- purified water,
- anhydrous glucose,
- benzalkonium chloride,
- disodium edetate,
- hydrochloric acid or sodium hydroxide (for pH-adjustment).

What Nasacort looks like and contents of the pack

Nasacort is a nasal spray suspension. It comes in a white plastic bottle which has a pump to spray Nasacort into your nostril through the spray nozzle. The bottle has a protective blue cover to keep the nozzle clean and a blue plastic clip to stop it from spraying accidentally.



This one spray bottle holds at least 120 sprays (16.5g of suspension which contains 9.075 mg triamcinolone acetonide) or at least 30 sprays (6.5g of suspension which contains 3.575 mg triamcinolone acetonide).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder :

In the United Kingdom:

Sanofi-aventis, One Onslow Street, Guildford, Surrey GU1 4YS, United Kingdom

Manufacturer:

Aventis Pharma, 72 London Road, Holmes Chapel, Crewe, Cheshire, CW4 8BE, United Kingdom

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THIS MEDICAMENT

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.