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PACKAGE LEAFLET: INFORMATION FOR THE USER

Nasacort[®]

Allergy Relief for Adults 55 micrograms/dose. nasal spray suspension Triamcinolóne acetonide

sanofi

(Referred to as Nasacort Allergy in the remainder of the leaflet)

Read all of this leaflet carefully before you start using this medicine, because it contains important information for you

This medicine is available without prescription. However, you still need to use Nasacort Allergy carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- Talk to your doctor if your symptoms worsen or do not improve after
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1. What Nasacort Allergy is and what it is used for
- 2. What you need to know before you use Nasacort Allergy
- 3. How to use Nasacort Allergy
- 4. Possible side effects
- 5. How to store Nasacort Allergy
- 6. Contents of the pack and other information

1. What Nasacort Allergy is and what it is used for

Nasacort Allergy 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 as a spray in the nose to treat the symptoms of seasonal allergic rhinitis (hayfever), such as sneezing, itchy and runny nose, itchy, red and watery eyes, nasal congestion and associated sinus discomfort. This type of allergy, such as hayfever, 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

2. What you need to know before you use Nasacort Allergy



Do not use Nasacort Allergy if:

- You are allergic (hypersensitive) to triamcinolone acetonide or any of the other ingredients of Nasacort Allergy (see Section 6). Signs of an allergic reaction to Nasacort Allergy include: a rash (hives), itching, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have an infection in the nose.
- You are taking medicines for HIV.

Warnings and precautions

Talk to your doctor or pharmacist before using Nasacort Allergy if:

- You have any infection of the nose or throat that is not treated. If you get a fungal infection while using Nasacort Allergy, 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 using other corticosteroid products, such as other nasal sprays or eye/nose drops, asthma medications, tablets creams or ointments.
- You are being transferred from steroid injections or tablets to Nasacort Allergy.
- You have had glaucoma or cataracts

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

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

If your symptoms do not improve after 7 days, or they are still not controlled, talk to your doctor or pharmacist.

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.

Other medicines and Nasacort Allergy

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

Some medicines may increase the effects of Nasacort Allergy and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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

Important information about some of the ingredients of Nasacort Allergy

Nasacort Allergy contains 15 micrograms benzalkonium chloride in each spray.

Benzalkonium chloride may cause irritation or swelling inside the nose. especially if used for a long time.

3. How to use Nasacort Allergy

You should check with your doctor or pharmacist if you are not sure about how to use Nasacort Allergy after reading this leaflet. 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 Allergy to use Adults (18 years and over)

- 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
- Use the lowest dose possible to control your symptoms
- If the symptoms do not improve or worsen within 7 days, talk to
- You should not use the spray every day for longer than one month without consulting your doctor

Children or adolescents under 18 years

This medicine is not recommended for children or adolescents under 18 years of age.

How to use the spray

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

1. Preparing the bottle

- Remove the blue cover 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 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 breathe 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
- Replace the cap over the nozzle















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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
- 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.



Bottle

Spray {

Nozzle`

Cap

Bottle

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 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 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

You should use only as directed in this leaflet or as your doctor or pharmacist has told you; using more or less may make your symptoms

If you use more Nasacort Allergy than you should

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 Allergy than you should.

If you forget to use Nasacort Allergy

If you have forgotten to use Nasacort Allergy, 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 Allergy

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



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 Allergy can cause side effects, although not everybody gets them.

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

• You have an allergic reaction to Nasacort Allergy. 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)
- Blurred vision

In some people, Nasacort Allergy 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nasacort Allergy

- Keep this medicine in a safe place where children cannot see or
- Do not use Nasacort Allergy 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.
- Nasacort Allergy should be used within 1 month after first opening
- 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. Contents of the pack and other information

What Nasacort Allergy contains

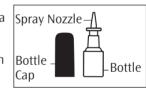
The active substance is triamcinolone acetonide. Each spray delivers 55 micrograms triamcinolone acetonide.

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 Allergy looks like and contents of the pack

Nasacort Allergy is a nasal spray suspension. It comes in a white plastic bottle which has a Spray Nozzle—\ pump to spray Nasacort Allergy into your nostril through the spray nozzle. The bottle has a protective cap to keep the nozzle clean |Bottle | and to stop it from spraying accidentally.



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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, United Kingdom

Tel: 0800 035 2525

Email: uk-medicalinformation@sanofi.com

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

This leaflet does not contain all of the information about your medicine. If you have any questions or are not sure about anything, ask vour doctor or pharmacist.

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