

PACKAGE LEAFLET

Package leaflet: Information for the user

Deflut 27,5 microgram/dosis, neusspray suspensie
fluticasone furoate

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for
2. What you need to know before you use <Invented name>
3. How to use <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information
Step-by-step guide to using the nasal spray

1. What <Invented name> is and what it is used for

<Invented name> (fluticasone furoate) belongs to a group of medicines called glucocorticoids. <Invented name> works to decrease inflammation caused by allergy (*rhinitis*) and therefore reduce symptoms of allergy.

<Invented name> nasal spray is used to treat symptoms of allergic rhinitis including stuffy, runny or itchy nose, sneezing and watery, itchy or red eyes, in adults and children aged 6 years and over.

Allergy symptoms can occur at specific times of the year and be caused by allergy to pollen from grass or trees (hayfever), or they can occur all year round and be caused by allergy to animals, house-dust mites or moulds to name some of the most common.

2. What you need to know before you use <Invented name>

Do not use <Invented name>

- If you are allergic to fluticasone furoate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Children and adolescents

Do not use in children under 6 years old.

Taking <Invented name>:

- may when taken for a long time cause children to grow more slowly. The doctor will check your child's height regularly, and make sure he or she is taking the lowest possible effective dose.
- may cause eye conditions such as glaucoma (increase in pressure in the eye) or cataracts (clouding of the lens of the eye). Tell your doctor if you had these conditions in the past, or if you notice blurred vision or other visual disturbances while you are taking <Invented name>.

Other medicines and <Invented name>

Tell your doctor or pharmacist if you are taking, or have recently taken, or might take any other medicines, including medicines obtained without a prescription.

It is especially important to tell your doctor if you are taking, or have recently taken any of the following medicines:

- steroid tablets or injected steroids
- steroid creams
- medicines for **asthma**
- ritonavir or cobicistat, used to treat **HIV**
- ketoconazole, used to treat **fungal infections**

Your doctor will assess whether you should take <Invented name> with these medicines. Your doctor may wish to monitor you carefully if you are taking any of these medicines as they may increase the side effects of <Invented name>.

<Invented name> should not be used at the same time with other nasal sprays containing steroids.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not use <Invented name> if you are pregnant, or planning to become pregnant, unless your doctor or pharmacist tells you to.

Do not use <Invented name> if you are breast feeding unless your doctor or pharmacist tells you to.

Driving and using machines

<Invented name> is unlikely to affect your ability to drive and use machines.

<Invented name> contains benzalkonium chloride

This medicine contains 8.25 micrograms of benzalkonium chloride per spray (27.5 micrograms).

Benzalkonium chloride may cause irritation or swelling inside of the nose, especially if used for a long time. Tell your doctor or pharmacist if you feel discomfort when using the spray.

3. How to use <Invented name>

Always use this medicine exactly as your doctor or pharmacist has told you. Don't exceed the recommended dose. Check with your doctor or pharmacist if you're not sure.

When to use <Invented name>

- Use once a day
- Use at the same time each day.

This will treat your symptoms throughout the day and night.

How long <Invented name> takes to work

Some people will not feel the full effects until several days after first using <Invented name>.

However, it is usually effective within 8 to 24 hours of use.

How much to use**Adults and children 12 years and over**

- The usual starting dose is 2 sprays in each nostril once every day.
- Once symptoms are controlled you may be able to decrease your dose to 1 spray in each nostril, once every day.

Children 6 to 11 years

- **The usual starting dose** is 1 spray in each nostril once a day.
- If symptoms are very bad your doctor may increase the dose to 2 sprays in each nostril once every day until the symptoms are under control. It may then be possible for the dose to be reduced to 1 spray in each nostril once every day.

How to use the nasal spray

<Invented name> has virtually no taste or smell. It is sprayed into the nose as a fine mist. Be careful not to get any spray into your eyes. If you do, rinse your eyes with water.

There is a step-by-step guide to using the nasal spray after Section 6 of this leaflet. Follow the guide carefully to get full benefit from using <Invented name>

See *Step-by-step guide to using the nasal spray*, after Section 6.

If you use more <Invented name> than you should

Talk to your doctor or pharmacist.

If you forget to use <Invented name>

If you miss a dose, take it when you remember.

If it is nearly the time for your next dose, wait until then. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, or if you have any discomfort using the nasal spray ask your doctor or pharmacist or nurse.

4. Possible side effects

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

Allergic reactions: get a doctor's help straight away

Allergic reactions to <Invented name> are rare and affect less than 1 person in 1,000. In a small number of people, allergic reactions can develop into a more serious, even life-threatening problem if not treated. Symptoms include:

- becoming very wheezy, coughing or having difficulty with breathing
- suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness)
- swelling around the face
- skin rashes or redness.

In many cases, these symptoms will be signs of less serious side effects. **But you must be aware that they are potentially serious** — so, if you notice any of these symptoms:

Contact a doctor as soon as possible.

Very common side effects (may affect more than 1 in 10 people)

- Nosebleeds (generally minor), particularly if you use <Invented name> for more than 6 weeks continuously.

Common side effects (may affect up to 1 in 10 people)

- Nasal ulceration – which may cause irritation or discomfort in your nose. You may also get streaks of blood when you blow your nose.
- Headache.
- Shortness of breath

Uncommon side effects (may affect up to 1 in 100 people)

- Pain, burning, irritation, soreness or dryness in the inside of the nose.

Very rare side effects (may affect up to 1 in 10,000 people)

- Small holes (perforations) in the ridge inside the nose that separates the nostrils.

Not known (frequency cannot be estimated from the available data)

- Slowing of growth in children.
- Blurred vision or temporary changes to vision with long term use.
- Chest tightness causing difficulty in breathing.

Nasal corticosteroids can affect the normal production of hormones in your body, particularly if you use high doses for a long time. In children this side effect can cause them to grow more slowly than others.

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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

Keep this medicine out of the sight and reach of children.

Always keep the cap on.

Do not use this medicine after the expiry date, which is stated on the label and carton. The expiry date refers to the last day of the month. <Invented name> nasal spray should be used within 2 months after first opening.

Do not refrigerate or freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Invented name> contains

- The active substance is fluticasone furoate. Each spray delivers 27.5 micrograms of fluticasone furoate.
- The other ingredients are glucose, microcrystalline cellulose (E460), carmellose sodium (E466), polysorbate 80 (E433), benzalkonium chloride, disodium edetate, water for injections (see section 2).

What <Invented name> looks like and contents of the pack

The medicine is a white nasal spray suspension contained in an amber glass bottle, fitted with a spray pump, applicator and a protective cap. <Invented name> is available in pack size of 120 sprays.

Marketing Authorisation Holder and Manufacturer

Day Zero ehf.
Reykjavíkurvegur 62
Hafnarfjörður
220
Iceland

Teva Czech Industries s.r.o.
Ostravská 305/29
Opava
Moravskoslezský
747 70
Czechia

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STEP-BY-STEP GUIDE TO USING THE NASAL SPRAY

What the nasal spray looks like

The nasal spray comes in an amber glass bottle fitted with a spray pump, applicator and a protective cap. It will contain 120 sprays.

Five important things you need to know about using the nasal spray

- <Invented name> comes in an amber glass bottle. If you need to check how much is left hold the nasal spray upright against a bright light. You will then be able to see the level through the bottle.
- When you **first use the nasal spray** you will need to **shake it vigorously** with the cap on for about 10 seconds. This is important as <Invented name> is a thick suspension that becomes liquid when you shake it well. It will only spray when it becomes liquid.
- The pump must be pressed all the way down, to release the mist through the nozzle.
- **Always keep the cap on the nasal spray** when you are not using it. The cap keeps the dust out, seals in the pressure and stops the nozzle from blocking up
- **Never use a pin** or anything sharp to clear the nozzle. It will damage the nasal spray.

Preparing the nasal spray for use

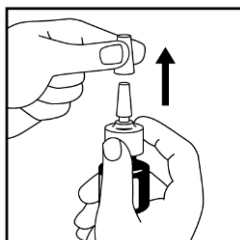
You must prepare the nasal spray:

- before you use it for the first time
- if you have left the cap off for 5 days or the intranasal device has not been used for 30 days or more.

Preparing the nasal spray helps to make sure you always get the full dose of medicine. Follow these steps:

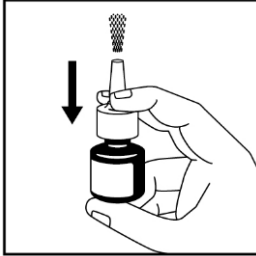
1. **Shake the nasal spray vigorously** with the cap on for about 10 seconds.
2. Remove the cap – see picture 1.

Picture 1



3. Hold the nasal spray upright, then tilt and **point the nozzle away from you.**
4. Prime the pump by putting two fingers on either side of the spray pump and place your thumb on the bottom of the bottle. Press down and release the pump. Do this at least 6 times until it releases a fine mist of spray into the air - see picture 2.

Picture 2



5. The nasal spray is now ready for use.

Using the nasal spray

1. **Shake the nasal spray** vigorously.
2. **Remove the cap.**
3. **Blow your nose** to clear your nostrils, then tilt your head forward a little bit.
4. Place the nozzle in one of your nostrils and close the other nostril with your finger – see picture 3. Point the end of the nozzle slightly outwards, away from the centre ridge of your nose. This helps to get the medicine to the correct part of your nose.
5. **Press the pump** firmly all the way down, **while you breathe in through your nose.**

Picture 3



6. Take the nozzle out and **breathe out through your mouth.**
7. If your dose is 2 sprays in each nostril repeat steps 4 to 6.
8. Repeat steps 4 to 7 to treat the other nostril.
9. **Replace the cap on the nasal spray.**

Cleaning the nasal spray

After each use:

1. Wipe the nozzle and inside of the cap with a clean, dry tissue.
2. Do not use water to clean it.
3. Never use a pin or anything sharp on the nozzle.
4. Always replace the cap once you have finished.

If the nasal spray does not seem to be working:

- Check you still have medicine left. Look at the level through the bottle. If the level is very low there may not be enough left to work the nasal spray.
- Check the nasal spray for damage
- If you think the nozzle may be blocked, don't use a pin or anything sharp to clear it.
- Try to reset it by following the instructions under 'Preparing the nasal spray for use'.

- If it is still not working, or if it produces a jet of liquid, take the nasal spray back to the pharmacy to get advice.