

27.5 micrograms per spray, Nasal Spray Suspension
fluticasone furoate

- 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.

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

Step-by-step guide to using the nasal spray

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.

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

- 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 Flutikaz.

Do not use Flutikaz if you are breast-feeding unless your doctor or pharmacist tells you to.

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

Very rare (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
- voice disorder, voice loss
- taste disorder, taste loss, smell loss.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website 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 Flutikaz

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. Flutikaz 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 Flutikaz 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 (see section 2), disodium edetate and water for injections.

What Flutikaz 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. Flutikaz is available in a pack size of 120 sprays.

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom
Manufacturer: Teva Czech Industries s.r.o, Ostravska 305/29, 747 70 Opava - Komarov, 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

- Flutikaz 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 Flutikaz 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

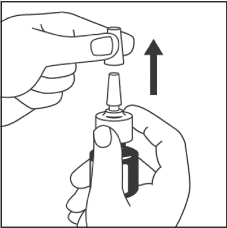
You must prepare the nasal spray:

- 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:

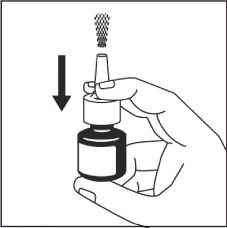
1. **Shake the nasal spray vigorously** with the cap on for about 10 seconds.
2. Remove the cap - see picture 1.

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, do not 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.

Annotations

ID	Page	Date	First Name	Last Name	Content
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Approvals

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