Package leaflet: Information for the user

Fluticasone propionate Alissa 50 microgram/actuation nasal spray, suspension

fluticasone propionate

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 or pharmacist.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Fluticasone propionate Alissa is and what it is used for

Fluticasone propionate Alissa contains fluticasone propionate, a corticosteroid, which reduces the inflammation and symptoms caused by an allergy.

Fluticasone propionate Alissa is used in adults and adolescents aged 12 years and older and in children aged 4 to 12 years to prevent and treat swelling and irritation inside the nose due to hay fever or allergies to pets, dust mites and mould spores (allergic rhinitis) as well as swelling and irritation inside the nose not caused by allergies.

Symptoms include a blocked, runny or itchy nose, sneezing and itchy or red eyes.

It may take 3 or 4 days for this medicine to work. So, keep using it, even though you may not feel better straight away.

2. What you need to know before you use Fluticasone propionate Alissa

Do not use Fluticasone propionate Alissa:

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

Warnings and precautions

Talk to your doctor or pharmacist before using Fluticasone propionate Alissa.

- if you have an infection in your nose.
- if you already use systemic steroids. If you change to Fluticasone propionate Alissa this must be done gradually, as your doctor has told you.

Talk to your doctor if you experience

- blurred vision or other visual disturbances.
- side effects that affect the whole body (systemic side effects);

  When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body. These effects are much less likely to occur than with oral corticosteroids and may vary for individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, cataract, glaucoma and, more rarely, effects on a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression.

Children and adolescents

Treatment with nasal corticosteroids (like Fluticasone propionate Alissa) for long periods of time may result in growth retardation.

Your doctor will monitor your child's height regularly and ensure that your child receives the lowest effective dose.

Other potential systemic side effects may include depression or aggression.

Other medicines and Fluticasone propionate Alissa

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

This is important if you are taking any medicines, particularly:

- if you are taking corticosteroid medicines (including tablets, creams, ointments, asthma inhalers, nasal sprays and eye or nasal drops).
- if you are taking a type of antiviral medicine known as a protease inhibitor (e.g. ritonavir) or cobicistat containing products which may increase the effects of fluticasone propionate. Your doctor may want to monitor you carefully if you are taking these medicines.
- if you are taking certain medicines used to treat fungal infections (e.g. ketoconazole).

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 or pharmacist for advice before taking this medicine.

Driving and using machines

Fluticasone propionate Alissa may cause blurred vision or other visual disturbances. If you are affected you should avoid activities such as driving and using machines.

Fluticasone propionate Alissa contains benzalkonium chloride

This medicine contains 20 microgram benzalkonium chloride per dose. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. How to use Fluticasone propionate Alissa

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dose

Adults and adolescents (aged 12 years and older)

- The recommended dose is two sprays into each nostril once a day, preferably in the morning.
- If required, your doctor may tell you to use two sprays in each nostril twice daily.

The maximum daily dose is four sprays per nostril.

Use in children and adolescents

Children aged 4 to 12 years

- The recommended dose is one spray into each nostril once a day, preferably in the morning.
- In some cases, one spray in each nostril twice daily may be required.

The maximum daily dose is two sprays per nostril.

Children under 4 years of age

Do not use in children under 4 years of age.

Continued overleaf

Method of administration

For nasal use only. Avoid eye contact.

Preparation of the nasal spray

If you have a new bottle or a bottle that you have not used for some time, you have to prepare the spray to ensure you get a correct dose. Prepare the spray by following the next steps:

1. Shake the bottle and remove the dust cap.
2. Hold the bottle upright and spray into the air;
   - 5 times if you have a new bottle.
   - 1 time if you have not used the bottle for some time.

Using the nasal spray

1. Shake the bottle and remove the dust cap.
2. Blow your nose.
3. Close one nostril with your finger and put the nozzle in the other nostril. Tilt your head forward slightly and keep the bottle upright.
4. Start to breathe in slowly and gently through your nose whilst pressing down the collar firmly with your fingers.
5. Breathe out through your mouth.
6. Repeat step 3 through 5 for the other nostril.

Cleaning the nasal spray

After each use:

1. Remove the dust cap. Do not remove the nozzle!
2. Clean the nozzle and inside of the dust cap with a dry and clean tissue.

Once a week:

1. Remove the dust cap. Do not remove the nozzle!
2. Wash the dust cap and the nozzle with water and allow to dry at room temperature.

Duration of treatment

Use this medicine regularly. It may take 3 or 4 days for this medicine to work. So, keep using it, even though you may not feel better straight away.

If you forget to use Fluticasone propionate Alissa

Do not use a double dose to make up for a forgotten dose.

If you miss a dose, just use the next dose when you remember it. Unless it is almost time for your next dose. In that case, just use the next dose when it is due.

If you stop using Fluticasone propionate Alissa

It may take 3 or 4 days for this medicine to work. So, keep using it regularly, even though you may not feel better straight away. Do not stop unless your doctor tells you to stop as your symptoms may return.

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

4. Possible side effects

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

Stop taking this medicine and seek urgent medical advice straight away if you experience any of the following side effects:

- Hypersensitivity reactions
- Serious allergic reaction which causes difficulty in breathing or dizziness (anaphylactic reaction, anaphylactoid reaction)
- Difficulty in breathing due to narrowing of the airways (bronchospasm)
- Swelling (oedema) of the face and tongue
- Skin rash
- Increased ocular pressure (glaucoma), increased pressure in the eye (intra-ocular pressure), cataract
- Holes in the ridge inside the nose that separates the nostrils (nasal septum perforation)
- Nose bleeds

Other side effects that may occur include:

Common (may affect up to 1 in 10 people)

- Headache
- Unpleasant taste or smell
- Dryness or irritation in the nose or throat

Unknown (cannot be estimated from the available data)

- Blurred vision
- Ulcers in the nose

When corticosteroids nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body (see section 2).

Additional side effects in children and adolescents

Growth retardation has been reported in children when corticosteroid nasal sprays are used (see section 2 under 'Children and adolescents'). Fluticasone propionate is a corticosteroid.

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 Yellow Card Scheme.

Website: 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 Fluticasone propionate Alissa

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

Store upright.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

After opening the bottle it expires after 3 months. Note the date of first opening on the label.

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 Fluticasone propionate Alissa contains

- The active substance is fluticasone propionate. Each dose contains 50 micrograms of fluticasone propionate.
- The other ingredients are benzalkonium chloride, glucose, microcrystalline cellulose (E460i) and carmellose sodium (E466), phenylethyl alcohol, polysorbate 80, purified water.

What Fluticasone propionate Alissa looks like and contents of the pack

Fluticasone propionate Alissa is a white opaque suspension.

Fluticasone propionate Alissa is packaged in a bottle with spray pump and dust cap and is available in packs containing 60, 120 or 150 sprays.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

Alissa Healthcare Research Ltd.
Unit 5, Fulcrum 1
Whiteley, Fareham
Hampshire PO15 7FE
United Kingdom

Manufacturer

Basic Pharma Manufacturing B.V.
Burgemeester Lemmensstraat 352
6163 JT Geleen
The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands	Fluticasonpropionaat Interdos, 50 microgram/dosis, neusspray, suspensie
United Kingdom	Fluticasone propionate Alissa 50 microgram/actuation nasal spray, suspension

This leaflet was last revised in November 2021