

FLOMIST AQUEOUS NASAL SPRAY ®

Fluticasone propionate (50 mcg per spray)

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What FLOMIST is used for

Flomist is used to prevent and treat inflammation in the lining of your nose (rhinitis) due to:

- Seasonal allergies, such as hay fever
- year round (perennial) allergies, such as animal allergies.

How FLOMIST works

Flomist contains a medicine called fluticasone propionate. This belongs to a group of medicines called steroids (also called 'cortico-steroids').

- Steroids work by reducing inflammation.
- They reduce swelling and irritation in your nose.
- This helps to relieve itching, sneezing and your blocked or runny nose.

Before you use FLOMIST

- When you must not use it

Do not use Flomist if:

You are allergic to fluticasone propionate or any of the other ingredients of this medicine

- Before you start to use it

Talk to your doctor or pharmacist before using Flomist:

- If you have ever had an operation on your nose.

- If you have an infection in your nose

- Taking other medicines

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

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

- you have had steroids for a long time, either as an injection or by your mouth
- you are taking some medicines for HIV such as cobicistat or ritonavir.

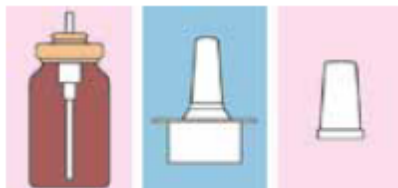
Taking Flomist with food and drink

- You can use Flomist with or without food.

How to use FLOMIST

Instructions for use

Parts of Flomist



**Bottle with Nozzle Dust Cap
Metered- Dose Atomising
Pump**

Before using

1. Shake the bottle gently, then remove the dust cap.
2. Hold the bottle as shown with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle.



3. **Before using your Flomist for the first time, or if you have not used it for a period of time, follow the instructions given below.**

With the nozzle pointing away from you, press several times as shown until a fine uniform mist comes out of the nozzle.



4. Blow your nose gently.



5. Close one nostril and put the nozzle in the other nostril as shown. Tilt your head slightly forward keeping the nozzle in the upright position.
6. Start to breathe in through your nose and while breathing in press down with your fingers once to release a spray.



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7. Breathe out through your mouth. Repeat steps 6 and 7 to inhale a second spray



8. Repeat steps 5, 6 and 7 for the other nostril



After use:

9. Wipe the nozzle with a clean cloth and replace the dust cap.



Note:

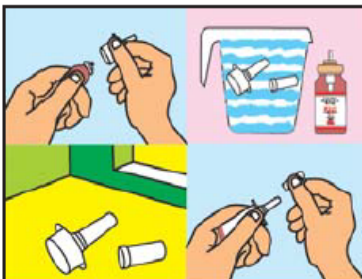
The first time you use Flomist, you may sneeze a few times. This is because the lining of your nose is very sensitive. This is not likely to happen after the first few doses.

This medication can, at times cause a few side-effects in certain hypersensitive individuals. If you notice any bleeding from your nose or experience any other discomfort, please inform your doctor.

Cleansing

Your Flomist should be cleaned at least once a week.

To do this:



1. Push the nozzle upwards to detach from the bottle.
2. Wash the nozzle and dust cap in warm water. Shake off excess water and leave to dry in a warm place. Avoid excessive heat.
3. Replace the nozzle and dust cap.
4. If the nozzle becomes blocked remove as above and soak in warm water. Rinse under a cold tap. Allow to dry and refit.

Do not use a pin or other sharp objects to unblock the nozzle.

Important

1. Use your Flomist as directed by your physician. Do not exceed the recommended dose.
2. It takes a few days for this medicine to work hence it is very important that you use it regularly. Do not stop treatment even if you feel better unless told to do so by your doctor.
3. This medicine has been specially recommended by your doctor for you. Do not allow any other person to use it.

- How much to use it

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

- Do not use in children under 4 years old.

Adults and children over 12 years

- The usual starting dose is 2 sprays into each nostril once a day, preferably in the morning.
- The most you would use over 24 hours is normally 8 sprays (4 sprays per nostril).
- As you become better, your doctor may ask you to use a lower dose - one spray into each nostril once a day.
- If your symptoms then get worse, your dose may be increased back to the starting dose.

Children 4 -11 years

- The usual starting dose is one spray into each nostril once a day, preferably in the morning.
- The most your child would use over 24 hours is normally 4 sprays (2 sprays per nostril).

If you use high doses of Flomist

You may need extra steroids:

- in times of extreme stress
- during admission to hospital after a serious accident or injury
- before a surgical operation.

Your doctor may give you extra steroid medication such as tablets or an injection.

-When to use it

Use the spray every day at the same time.

- How long to use it

If you stop taking Flomist

Do not stop treatment even if you feel better, unless your doctor tells you to stop. If you do stop, the symptoms may come back.

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

- If you forget to use it

If you miss a dose, just use the next dose when it is due. Do not take a double dose to make up for the forgotten dose.

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-If you use too much (overdose)

Tell your doctor if you use more than you were told to.

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.

While you are using FLOMIST

- Things you must do

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.

- Things you must not do

- Only use in your nose, contact with eyes should be avoided.

- Things to be careful of

Driving and using machines

If you feel dizzy or tired, do not drive or operate machines.

Administration of corticosteroids through nose may cause children to grow more slowly. Children should use the recommended lowest dose and for the shortest duration. Children who receive this treatment for a long period of time will have their height checked regularly by their doctor.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions: get a doctor's help straight away

A small number of people get allergic reactions to Flomist, which 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, mouth or tongue
- skin rashes or redness

If this happens, tell your doctor straight away– you may need urgent medical treatment.

Allergic reactions to fluticasone nasal spray are very rare (These affect less than 1 in 10,000 people).

Immediately after you use your spray

- You may sneeze a little, but this soon stops.
- You may find you get an unpleasant taste or smell.

Tell your doctor as soon as possible if you notice any of the following side effects:

Other side effects include:

Very common

- Nose bleeds.

Common

- Headache.
- Unpleasant taste.
- Unpleasant smell.
- A dry or irritating nose or throat.
- Pneumonia (infection of the lung) in people with chronic obstructive pulmonary disease (COPD). Tell your doctor if you have any of the following while taking Flomist, they could be symptoms of a lung infection:

- Fever or chills;
- Increased mucus production or change in mucus colour;
- Increased cough or increased breathing difficulties.

Very rare

- Skin reaction

- Facial or mouth swelling

Very rarely, the normal production of steroids in your body may be affected. This is more likely to happen if you use high doses for a long time. Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for adverse Drug Reaction monitoring by visiting the web site: npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of FLOMIST

-Storage

Keep out of the sight and reach of children.

- Store below 30°C.
- Protect from frost and light.
- Do not put in a refrigerator.
- 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.

-Disposal

If you are told to stop taking this medicine return any unused spray to your pharmacist to be disposed.

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.

Product description

- What it looks like

A white uniform, homogenous, redispersible suspension filled in white opaque HDPE vial with crimped nasal spray of 100 metered dose.

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Fluticasone propionate (50 mcg per spray)

- Ingredients

- Active substance is Fluticasone propionate

- Inactive ingredients are Microcrystalline cellulose and carboxymethylcellulose sodium, Polysorbate 80, Dextrose Anhydrous, Benzalkonium chloride, Phenylethyl alcohol, sodium hydroxide and water for injection

-MAL Number

MAL07090921AZ

Manufacturer

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Product Registration Holder

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