

FLUTIFLOW 120 (Fluticasone Nasal Spray BP 50mcg)

FLUTICASONE PROPIONATE, 50mcg

What is in this leaflet

1. What FLUTIFLOW 120 is used for
2. How FLUTIFLOW 120 works
3. Before you use FLUTIFLOW 120
4. How to use FLUTIFLOW 120
5. While you are using FLUTIFLOW 120
6. Side effects
7. Storage and disposal of FLUTIFLOW 120
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What FLUTIFLOW 120 is used for

FLUTIFLOW 120 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.

In patients with allergic rhinitis, FLUTIFLOW 120 is also indicated for the management of associated sinus pain and pressure.

How FLUTIFLOW 120 works

FLUTIFLOW 120 belongs to a group of medicines called corticosteroid (steroid for short) which has an anti-inflammatory action. The tiny amounts sprayed into your nose help to reduce swelling and irritation.

Ask your pharmacist or doctor if you have any questions about this medicine.

Before you use FLUTIFLOW 120

-When you must not use it

Do not use this medicine if:

- you have an allergy or have had an adverse reaction to any of this medicine related

ingredients.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use this medicine:

- after the expiry date printed on the pack, or
- if the packaging is torn or shows signs of tampering.

-Before you start to use it

Tell your doctor or pharmacist:

- Your medical conditions or allergies you may have, and any significant facts about your health
- If you have infection of the nasal (nose) airways.

Pregnancy and breast feeding:

- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant, plan to become pregnant or breastfeeding.
- Safe use during pregnancy and breastfeeding has not been established.

-Taking other medicines

Check with your doctor or pharmacist before using this medicine:

- if you are taking ritonavir or cobicistat (a medicine used to treat HIV).
- if you are using ketoconazole (used to treat fungal infections).
- If you are using other corticosteroid medicines – these may include some eczema creams, asthma inhalers, tablets, injections, nasal sprays, and eye or nose drops.

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.

How to use FLUTIFLOW 120

-How much to use

FLUTIFLOW 120 is for administration by the intranasal route only.

- **Adults and children 12 years and over:** The recommended dose is two sprays into each nostril once a day, preferably in the morning. Once control is achieved the dose should be titrated down to one spray in each nostril once a day (100 micrograms per day). In some cases two sprays into each nostril twice daily may be required for short periods to achieve control of symptoms, after which the dose should be titrated down. The maximum daily dose should not exceed four sprays into each nostril.
- **Children 4 to 11 years old:** The recommended dose is one spray into each nostril once a day, preferably in the morning. The maximum daily dose should not exceed one spray into each nostril.
- **Children under 4 years old:** Do not use.
- **Elderly:** The normal adult dosage is applicable.

Onset of action in the treatment of allergic rhinitis has been observed in some patients as early as 2-4 hours after use, with most users achieving symptomatic relief within 12 hours of treatment.

Prophylaxis of allergic rhinitis requires treatment before contact with allergen.

For full therapeutic benefit daily usage is essential over the recommended treatment duration. Maximum benefit may require 3-4 days of continuous treatment in some people.

How to use the spray:

1. Blow the nose gently to clear nostrils.

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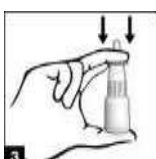
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2. Shake the bottle gently.



3. For first time use, hold the bottle upright and fill the pump by pressing the nozzle downwards and releasing it 5 times, until a fine spray is produced.



4. Close one nostril with one finger. Hold the bottle upright and insert the nozzle into the nostril as far as is comfortable. Whilst breathing in gently through the nose with the mouth closed, press the bottle upwards once to deliver one spray.



5. Breathe out through the mouth.



6. Repeat steps 4 and 5 for the other nostril.
7. For patients aged 12 years and older, steps 4, 5 and 6 should be repeated once more to achieve recommended dosage of 2 sprays into each nostril.

8. To keep the spray nozzle clean, wipe it carefully with a clean tissue after each use and replace the cap.



If the nasal spray has not been used for 2 weeks or more, spray once into the air before use. Point the nozzle away while doing this.

Always shake the bottle gently before use. If the spray does not work and it may be blocked, clean it as follows. NEVER try to unblock it or enlarge the tiny spray hole with a pin or other sharp object because this will destroy the spray mechanism.

The nasal spray should be cleaned at least once a week or more often if it gets blocked.

How to clean the spray:

1. Remove the cap and pull off the spray nozzle only.
2. Soak the dust-cap and spray nozzle in warm water for a few minutes, and then rinse under cold running tap water.
3. Shake or tap off the excess water and allow to air-dry.
4. Re-fit the spray nozzle.
5. Prime the unit as necessary until a fine mist is produced and use as normal.

-When to use it

It is preferably to administer the sprays in the morning.

-How long to use it

Follow carefully all directions given to you by your doctor and the pharmacist.

If you are not sure how long you should be using FLUTIFLOW 120, check with your doctor. If your condition does not improve after the treatment course, or if it becomes worse, contact your doctor.

-If you forget to use it

It is important to use this medication exactly as prescribed by your doctor. If you forget to apply this medication, apply it as soon as you remember. If it is almost time for your next application, skip the missed dose and continue with your regular schedule. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

There is no available data on the effects of overdosage with FLUTIFLOW 120. Long term usage of corticosteroid may cause suppression of HPA axis function (resulting in inadequate cortisol 'stress hormone' production).

If you suspect that you are overdosed, please consult your pharmacist or doctor. Bring any remaining medicine with you.

While you are using FLUTIFLOW 120

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell your doctor immediately if you become pregnant while taking this medication.

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking FLUTIFLOW 120.

-Things you must not do

Do not continue FLUTIFLOW 120 if you have irritation or sensitization after using this medicine.

Do not exceed maximum daily dose. Ask your doctor or pharmacist.

Do not give this medication to anyone else, even if they have the same symptoms as you do. It can be harmful for people to use this medication if their doctor has not prescribed it.

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-Things to be careful of

This medication should not be used in or near eye area. If this occurs, bathe your eye with eyewash if possible. Your eye may sting. If you start having any problem with your sight or your eye is sore, contact your doctor immediately.

Do not swallow this medication. Small quantity may not cause any harm. If you accidentally swallow in a larger quantity, please contact your doctor immediately.

Side effects

Like other medicines, FLUTIFLOW 120 can cause some side effects.

Stop applying FLUTIFLOW 120 and immediately contact your doctor if you notice any of the following symptoms. You may be having an allergic reaction.

- severe and sudden onset of itching, redness, hives or a rash around the application area
- swelling of the face, lips, mouth, tongue or throat with breathing difficulties.

Other possible side effects which are common can also occur. You should tell your doctor about these as soon as possible.

- Irritation or dryness of the site of treatment especially the nose and throat
- Headache
- Unpleasant taste or smell

Hypersensitivity (allergy) to Fluticasone propionate or the ingredients of the nasal spray.

Other possible side effects can also occur. You should tell your doctor about these as soon as possible.

If you get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to

the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of FLUTIFLOW 120

-Storage

Do not store above 30°C.

-Disposal

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.

Product Description

-What it looks like

FLUTIFLOW 120 is White colored suspension filled in amber vial fitted with crimp on pump, actuator and dust cap.

-Ingredients

Active ingredient:
Fluticasone propionate

Inactive ingredients:
Benzalkonium Chloride 50%, Phenylethyl Alcohol, Dextrose Anhydrous, Microcrystalline Cellulose & Sodium Carmellose (Avicel RC 591), Polysorbate 80, Hydrochloric Acid and Water for Injection.

-MAL number: MAL25016022AZ

Manufacturer:

Zydus Lifesciences Limited
Survey No. 417, 419 & 420, Sarkhej
- Bavla National Highway No. 8A,
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Dist. - Ahmedabad - 382210,
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Product Registration Holder:

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