

FLUTIMATE NS 50 (Fluticasone Nasal Spray BP 50mcg)

Fluticasone propionate 0.05% w/w (Fluticasone propionate BP 50 mcg per actuation)

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What FLUTIMATE NS is used for

FLUTIMATE NS 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.

FLUTIMATE NS is used to prevent and treat:

- Inflammation in the lining of your nose (rhinitis) due to seasonal allergies, such as Hayfever.
- Inflammation in the lining of your nose (rhinitis) due to year round (perennial) allergies, such as animal allergies.

How FLUTIMATE NS works

Fluticasone propionate is a synthetic, trifluorinated corticosteroid, it has local anti-inflammatory and anti-allergic activity.

Before you use FLUTIMATE NS

-When you must not use it

- **Do not use FLUTIMATE NS if you have ever had an allergic reaction to fluticasone propionate or any of the ingredients.**

Read the side effects section to find out the symptoms of an allergic reaction to FLUTIMATE NS.

- **Do not use FLUTIMATE NS if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor or pharmacist says you should.**
- **Do not use FLUTIMATE NS after the expiry date (EXP) printed on**

the pack.

- **If you use the product after the expiry date has passed, it may not work as well.**

- **Do not use FLUTIMATE NS if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be using FLUTIMATE NS, talk to your doctor or pharmacist.

-Before you start to use it

You must tell your doctor or pharmacist if:

- **You have an infection in your nose or sinuses**
- **You have had nasal surgery**
- **You have been treated with steroid injections, or taken steroid tablets.**
- **You are allergic to foods, dyes, preservatives or any other medicine**

-Taking other medicines

Please tell your doctor if you are taking or have recently taken 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 a type of antiviral medicine known as a protease inhibitor (e.g. ritonavir)
- you are taking certain medicines used to treat fungal infections (e.g. ketoconazole).
- Some medicines may increase the effects of FLUTIMATE NS and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

How to use FLUTIMATE NS

-How much to use

Always use FLUTIMATE NS exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- **Do not use in children under 4 years old**
- **Only use in your nose**
- **It takes a few days for this medicine to work. So keep using it, even though you may not feel better straight away.**

- Use the spray every day.

Adults and children (aged 12 and over)

- 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 aged 4 to 11 years

- The usual starting dose is one spray into each nostril once a day, preferably in the morning.

- The most you would use over 24 hours is normally 4 sprays (2 sprays per nostril)

-When to use it

Use FLUTIMATE NS at the same time each day, preferably in the morning.

-How long to use it

Continue to use FLUTIMATE NS regularly for as long as your doctor or pharmacist tells you to.

-If you forget to use it

If you miss a dose, just use the next dose when it is due.

-If you use too much (overdose)

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

While you are using it

-Things you must do

Tell your doctor or pharmacist that you are using FLUTIMATE NS if you are about to be started on any new medicines.

Tell your doctor or pharmacist if, for any reason, you have not used your medicine exactly as instructed.

Otherwise, your doctor or pharmacist may think that it was not effective and change your treatment unnecessarily.

Use FLUTIMATE NS only in your nose.

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-Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use FLUTIMATE NS to treat any other complaints unless your doctor or pharmacist says so.

-Things to be careful of

- If you have ever had an operation on your nose.
- If you have an infection in your nose
- If you are unsure if the above apply to you, talk to your doctor or pharmacist before using FLUTIMATE NS.

Side effects

Like all medicines, FLUTIMATE NS 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 FLUTIMATE NS, 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.

Immediately after you use your spray

- Very occasionally you may find you get an unpleasant taste or smell.

Other side effects:

Very common

- Nose bleeds.

Common

- Headache.
- Unpleasant taste.
- Unpleasant smell.
- A dry or painful nose or throat.

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 from happening by making sure you use the lowest dose of steroids which controls your symptoms.

In children this side effect can rarely cause them to grow more slowly than others. Children who receive this treatment for a long period of time will have their height checked regularly by their doctor.

If you notice any side effects not listed in this leaflet tell your doctor as soon as possible.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of FLUTIMATE NS

-Storage

Keep out of the reach and sight of children.

- Protect from frost and light.
- Do not store above 30°C.
- Do not put in a refrigerator.
- Do not use FLUTIMATE NS 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.
- If you are told to stop taking this medicine return any unused spray to your pharmacist to be destroyed.

-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

FLUTIMATE NS comes in a brown glass bottle fitted with a pump, nasal adaptor and dust cover. Each bottle provides approximately 120 sprays, when used as recommended.

-Ingredients

-Active ingredient

Fluticasone propionate.

- Inactive ingredients

Anhydrous glucose, microcrystalline cellulose and carboxymethylcellulose sodium, phenylethyl alcohol, benzalkonium chloride, polysorbate 80, dilute hydrochloric acid and purified water.

-MAL number:

MAL14125126AZ

Manufacturer

Jewim Pharmaceutical (Shandong) Co., Ltd.

Tai'an High-Tech Industrial Development Zone, Shandong Province, PRC

Product Registration Holder

Medispec (M) Sdn Bhd
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