

# Budemate NS 64 (Budesonide Aqueous Nasal Spray BP 64mcg)

**Budesonide 64mcg/spray × 120sprays**

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## What BUDEMATE NS 64 is used for

BUDEMATE NS contains a medicine called budesonide. This belongs to a group of medicines called corticosteroids.

- Corticosteroids help to prevent inflammation.
- BUDEMATE NS is used to treat the effects of allergies, such as hay fever, and inflammation inside the nose (rhinitis).
- It can also stop these effects from coming on.
- It is also used to treat small growths inside the nose (nasal polyps).

## How BUDEMATE NS 64 works

Allergies occur when the body's immune system reacts to normally harmless substances that do not bother most people. This immune system reaction is known as inflammation and involves several different types of cells and several different chemicals in the body.

Budesonide nasal spray is a corticosteroid, or simply "steroid" for short. Steroids can have many different effects in the body, including anti-inflammatory effects. Steroids decrease inflammation by limiting the body's ability to produce an immune system reaction. They can be effective for treating conditions such as allergies. However, long-term use of steroids can cause bothersome and sometimes serious side effects, and this limits their usefulness. Because budesonide is a nasal spray, its effects are generally limited to the nose. This helps prevent many of the long-term side effects of steroids.

## Before you use BUDEMATE NS 64

### When you must not use it

You are allergic (hypersensitive) to budesonide or any of the other ingredients of BUDEMATE NS.

If you are not sure if this applies to you, talk to your doctor or pharmacist before using BUDEMATE NS.

### Pregnancy and lactation

- If you are pregnant or planning to get pregnant, talk to your doctor or pharmacist before using BUDEMATE NS.
- If you get pregnant while using BUDEMATE NS, talk to your doctor straight away.
- If you are breast-feeding, talk to your doctor or pharmacist before using BUDEMATE NS.

### Before you start to use it

Before you use BUDEMATE NS, tell your doctor or pharmacist if:

- You have TB (tuberculosis).

If you are not sure if either of the above apply to you, talk to your doctor or pharmacist before using BUDEMATE NS.

### Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

In particular, talk to your doctor if:

- You are taking medicines to treat fungal infections (such as itraconazole or ketoconazole).
- You have been taking steroid tablets. Your doctor may ask you to take fewer of them after starting to use BUDEMATE NS. If you notice any unusual effects as a result of this, tell your doctor.

Some medicines may increase the effects of BUDEMATE NS 32 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 BUDEMATE NS 64

### How much to use

Rhinitis (hay fever)

- The usual dose for adults and children from 6 years is two sprays of BUDEMATE NS into each nostril in the morning. Alternatively, your doctor may ask you to take one spray of BUDEMATE NS into each nostril every morning and evening.
- This may be reduced by your doctor once your symptoms have improved.

It is important to use BUDEMATE NS regularly. Try to use it before you come into contact with whatever causes the allergy. For example, pollen is what causes hay fever, so you will be more at risk outdoors.

### Nasal polyps

- The usual dose is two sprays of BUDEMATE NS into each nostril every morning or one spray into each nostril every morning and evening.

You may not notice any effects of the medicine for the first few days. Don't stop taking it. Keep taking the medicine as you have been told to. If you still feel no different after a few more days, talk to your doctor.

### When to use it

It is usually used once a day, or two times a day respectively in the morning and evening.

### How long to use it

Do not stop using BUDEMATE NS until your doctor or pharmacist tells you to. BUDEMATE NS helps control your condition. You must keep using it every day for as long as your doctor or pharmacist advises, even if you are feeling better.

### If you forget to use it

If you forget to take a dose, take it as soon as you remember. However, if it is almost time to take the next dose, wait until then. Do not take a double dose to make up for a forgotten dose.

### If you use too much (Overdose)

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.

If you take too many doses of BUDEMATE NS, talk to your doctor or pharmacist straight away.

## While you are using it

### Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using BUDEMATE NS.
- Tell any other doctors, dentists, and pharmacists who treat you that you are using BUDEMATE NS.

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• If you become pregnant while taking BUDEMATE NS, tell your doctor immediately.

### Things you must not do

- Do not use BUDEMATE NS to treat any other complaints unless your doctor tells you to.
- Do not give BUDEMATE NS to anyone else, even if their symptoms seem similar to yours.

### Things to be careful of

Please read the package insert carefully or ask your doctor

### **Side effects**

Like all medicines, BUDEMATE NS can cause side effects, although not everybody gets them.

If any of the following happen to you, stop using BUDEMATE NS and talk to your doctor straight away:

- Skin rash, itching, lumpy rash (hives), blistering of the skin. Swelling of your face, lips, tongue or throat (this may make it difficult to swallow).
  - In addition to the above, sudden wheezing and/or feeling faint may occur. It is not known how often these occur; however they are very unlikely.
- If any of the above occurs, you may be having an allergic reaction.

Other possible side effects:

Common

- Occasional sneezing, dry nose, or stinging in your nose. These can happen straight after using BUDEMATE NS.

- Slight bleeding from the nose.

Very rare

- Sore patches on the inside of the nose.
- Perforation of the membrane separating the nostrils (the nasal septum).
- Severe allergic reaction.

If any of these side effects occur, they usually go away after a short time. If you notice any side effects get serious, or if you notice any side effects not listed in this leaflet, please 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.moh.gov.my](http://npra.moh.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### **Storage and Disposal of BUDEMATE NS 64**

#### Storage

Store below 30°C. Do not freeze. Keep away from sunlight and heat. Keep the bottle in an upright position.

#### Disposal

Discard in 2 months of initial use. 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?

BUDEMATE NS is a nasal spray suspension. Each spray delivers 64 mcg of budesonide. Each bottle of BUDEMATE NS contains 120 metered sprays after initial priming. This product is an aqueous suspension of Budesonide in a suitable container fitted with an appropriate nasal delivery system.

#### Ingredients

The active ingredient is: Budesonide

Inactive ingredients are: Dispersible cellulose, Anhydrous glucose, Polysorbate 80, Potassium sorbate, Disodium edetate, Hydrochloric acid and Purified water

#### **MAL. NO:**

MAL15025040AZ

#### **Manufacturer**

Jewim Pharmaceutical (Shandong) Co., Ltd.

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

#### **Product Registration Holder**

Medispec (M) Sdn Bhd

No.55&57, Lorong Sempadan 2, Ayer Itam, 11400, Penang, Malaysia.

#### **Date of Revision**

19/06/2024

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