

BUDAMAX[®]

Budesonide

Consumer Medicine Information

Name of consumer

Address of consume

What is in this leaflet

This leaflet answers some common questions about Budamax.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Budamax against the benefits they expect it will have for you.

If you have any concerns about using Budamax, ask your doctor or pharmacist.

Keep this leaflet with your Budamax.

You may need to read it again.

What BUDAMAX is used for

Allergic rhinitis (Hayfever)

Budamax is sprayed into the nose to help prevent and treat allergic rhinitis (hayfever). Hayfever is an inflammation or swelling of the nose lining (which may cause blockage, runny nose, itching and/or sneezing). This is often, but not always, due to an allergy to something in the air (eg pollen, dust mites).

You may have symptoms only during spring or summer. This type of allergy is generally due to various pollens. Some people

may experience symptoms all year round. This is usually caused by house dust mites, pets or moulds.

Nasal Polyps

Budamax is also used to treat nasal polyps, which are small masses of tissue that grow from the nose lining.

Budamax contains budesonide. This belongs to a family of medicines called corticosteroids, which are used to help reduce inflammation.

Ask your doctor if you have any questions about why Budamax has been prescribed for you.

Your doctor may have prescribed it for another reason.

Budamax is not addictive.

Budamax is available only with a doctor's prescription.

Before you use BUDAMAX

When you must not use it

Do not use Budamax if:

- 1. you have an allergy to:**
 - any medicines containing budesonide
 - any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body.

2. You have frequent nose bleeds.

Your condition may cause nose bleeds and still require treatment. Discuss with your doctor if you have any concerns.

3. You have severe nasal infections especially candidiasis (thrush).

Do not give Budamax to a child under the age of 6 years.

Budamax is not recommended for use in children under 6 years of age.

Do not use Budamax after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using Budamax, talk to your pharmacist or doctor.

Before you start to use it

Tell your doctor, if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- nasal, sinus or chest infection
- recent injury or surgery to your nose
- open sores in your nose
- severe nasal congestion or obstruction
- tuberculosis (TB)

It may not be safe for you to use Budamax if you have any of these conditions.

Tell your doctor if you are pregnant or plan to become pregnant, or breast-feeding.

Your doctor will discuss the possible risks and benefits of using Budamax during pregnancy and while breastfeeding.

If you have not told your doctor about any of the above, tell them before you start using Budamax.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Budamax may interfere with each other. These include:

- other corticosteroid medicines, such as tablets, asthma inhalers, nasal sprays, or eye/nose drops.
- medicines used to treat fungal infections (eg ketoconazole, itraconazole)
- cimetidine, a medicine used to treat reflux and stomach ulcers
- some antibiotic medicines (including erythromycin, clarithromycin).

These medicines may be affected by Budamax, or may affect how well it works. You may need different amounts of Budamax, or you may need to use a different

medicine. Your doctor or pharmacist will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Budamax.

How to use BUDAMAX

To prevent symptoms, start using Budamax:

- before the hayfever season; or
- before coming into contact with something you know will cause your hayfever.

If you start using Budamax early, it will help reduce the severity of your symptoms.

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

They may differ from the information contained in this leaflet.

How to use it

Each pack of Budamax contains an instruction leaflet that tells you the correct way to use it. Please read the leaflet carefully.

If you do not understand the instruction leaflet, ask your doctor or pharmacist for help.

Gently blow your nose before using Budamax.

Use only in your nose.

How much to use

Your doctor may tell you to use doses that are different to those outlined below. If so, follow your doctor's instructions.

HAYFEVER:

When you first start using Budamax:

- The usual starting dose is:
- TWO sprays into EACH nostril in the morning; or

- ONE spray into EACH nostril twice a day (in the morning and evening).

Do not exceed the recommended dose.

It may take a few days (in rare cases after 2 weeks) of using Budamax before you notice any improvement in your symptoms.

Once your symptoms improve:

After your hayfever has improved, your doctor may tell you to reduce the dose of Budamax. This may be ONE spray into EACH nostril in the morning.

NASAL POLYPS
(Adults 18 years and older):

The usual dose is:

- ONE spray into EACH nostril twice a day (in the morning and evening).

How long to use it

Continue using your Budamax for as long as your doctor tells you to.

If you forget to use it

If you miss a dose of Budamax, use it as soon as you remember.

Do not use a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor, pharmacist or the Poisons Information Centre (telephone 131 126) if you think you or anyone else may have used too much Budamax. Do this even if there are no signs of discomfort or poisoning.

While you are using BUDAMAX

Things you must do

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

They may differ from the information contained in this leaflet.

Keep all of your doctor's appointments so that your progress can be checked.

Ask your doctor to examine your nose from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Budamax.

Tell any other doctors, dentists, and pharmacists who treat you that you are using Budamax.

If you become pregnant while using Budamax, tell your doctor.

Things you must not do

Do not use Budamax to treat any other complaints unless your doctor tells you to.

Do not give Budamax to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Budamax.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- dizziness
- tiredness
- sneezing after spraying or irritated nose
- nose bleeds
- nasal crust
- dry nose or mouth
- itching or sore throat
- cough
- increased amount of sputum

The above list includes the more common side effects of your medicine. They are usually mild and only last for a short time.

Tell your doctor or pharmacist immediately if you notice any of the following:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- severe rash
- an ulcer (open wound) in your nose
- sign or symptoms of a nasal or sinus infection such as fever, pain or swelling, or discoloured nasal discharges.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Corticosteroids taken through the nose for long periods may affect how children grow. In rare cases, some children may be sensitive to the growth effects of

corticosteroids, so the doctor may monitor a child's height.

Ask your doctor to answer any questions you may have.

After using BUDAMAX

Storage

Keep your Budamax in a cool dry place where the temperature stays below 30°C. Do not freeze.

Do not store Budamax or any other medicine in the bathroom or near a sink. Do not leave it on window sills or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using Budamax or it has passed its expiry date, ask your pharmacist what to do with any you have left.

Product description

Budamax comes in a brown glass bottle containing approximately 120 doses, with metered pump spray equipment and nasal adaptor.

Budamax contains 64 micrograms of budesonide per dose as the active ingredient, and the following inactive ingredients:

- disodium edetate
- potassium sorbate (E202)
- glucose
- dispersible cellulose
- polysorbate 80 (E433)
- purified water.

Hydrochloric acid (E507) may have been added to adjust pH of the solution.

Sponsor

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Budamax 64 micrograms Nasal
Spray - AUST R 75659

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group of companies.