

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using BUDAMAX?

BUDAMAX contains the active ingredient Budesonide. BUDAMAX is used to prevent and treat allergic rhinitis. This is an inflammation or swelling of the nose lining which may cause blockage, runny nose, itching and/or sneezing. It is often caused by allergy.

For more information, see Section [1. Why am I using BUDAMAX?](#) in the full CMI.

### 2. What should I know before I use BUDAMAX?

Do not use if you have ever had an allergic reaction to Budesonide or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use BUDAMAX?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with BUDAMAX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use BUDAMAX?

- TWO sprays into EACH nostril in the morning; or ONE spray into EACH nostril twice a day (in the morning and evening).
- It may take a few days (in rare cases after 2 weeks) of using Budamax before you notice any improvement in your symptoms.
- Do not exceed the recommended dose.
- More instructions can be found in Section [4. How do I use BUDAMAX?](#) in the full CMI.

### 5. What should I know while using BUDAMAX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using BUDAMAX.</li><li>• Ask your doctor to examine your nose from time to time to make sure the medicine is working and to prevent unwanted side effects.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use Budamax to treat any other complaints unless your doctor tells you to.</li><li>• Do not give Budamax to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how BUDAMAX affects you</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your Budamax in a cool dry place where the temperature stays below 30°C. Do not freeze.</li></ul>

For more information, see Section [5. What should I know while using BUDAMAX?](#) in the full CMI.

### 6. Are there any side effects?

Side effects are usually mild and only last a short time. 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# BUDAMAX<sup>®</sup>

Active ingredient(s): Budesonide

## Consumer Medicine Information (CMI)

This leaflet provides important information about using BUDAMAX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BUDAMAX.**

**Where to find information in this leaflet:**

1. [Why am I using BUDAMAX?](#)
2. [What should I know before I use BUDAMAX?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use BUDAMAX?](#)
5. [What should I know while using BUDAMAX?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

### 1. Why am I using BUDAMAX?

**BUDAMAX contains the active ingredient Budesonide and is used to treat Allergic rhinitis.** BUDAMAX belongs to a family of medicines called corticosteroids, which are used to help reduce inflammation.

Allergic rhinitis 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 (e.g. pollen, dust mites).

You may have symptoms only during spring or summer. This type of allergy is generally due to various pollens and is commonly referred to as hayfever. Some people may experience symptoms all year round. This is usually caused by house dust mites, pets or moulds and is commonly referred to as perennial allergic rhinitis.

### 2. What should I know before I use BUDAMAX?

#### Warnings

**Do not use BUDAMAX if:**

- you are allergic to **Budesonide**, or other corticosteroids or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition
- you have frequent nose bleeds. These may be caused by your condition and still require treatment.
- you have severe nasal infections especially candidiasis (thrush)

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

- nasal, sinus or chest infection

- recent injury that has not healed or surgery to your nose
- open sores in your nose
- severe nasal congestion or obstruction
- tuberculosis (TB) or have been exposed to someone who has tuberculosis, chicken pox or measles
- glaucoma
- cataracts or have an eye infection
- diabetes

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

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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 for conditions such as asthma, allergies or skin rash. These may include 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BUDAMAX.**

## 4. How do I use BUDAMAX?

### How much to take

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

#### ALLERGIC RHINITIS/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 allergies have 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

- Adults and children 12 years and older.  
Continue using your Budamax for as long as your doctor tells you to.
- Children 6-12 years of age  
Talk to your child's doctor if your child needs to use the spray for longer than two months a year.

### 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.

### When to take / use BUDAMAX

#### To prevent symptoms, start using Budamax:

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

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

### If you forget to use BUDAMAX

BUDAMAX should be used regularly at the same time each day. If you miss your dose at the usual time, use it as soon as you remember.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

### If you use too much BUDAMAX

If you think that you have used too much BUDAMAX, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre
- (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using BUDAMAX?

### Things you should do

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

**If symptoms persist or worsen, or if new symptoms occur, stop use and see your doctor.**

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**

Remind any doctor, dentist or pharmacist you visit that you are using Budamax.

### Things you should 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.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how BUDAMAX affects you.**

BUDAMAX may cause dizziness in some people

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

## Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• Headache</li><li>• Dizziness</li><li>• Tiredness</li><li>• sneezing after spraying or irritated nose</li><li>• nose bleeds</li><li>• nasal crust</li><li>• dry nose or mouth</li><li>• itching or sore throat</li><li>• cough</li><li>• increased amount of sputum</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

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

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li><li>• severe rash</li><li>• an ulcer (open wound) in your nose</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b>

Serious side effects	What to do
<ul style="list-style-type: none"><li>• sign or symptoms of a nasal or sinus infection such as a persistent fever, pain or swelling, or discoloured nasal discharges.</li><li>• If you have any change in vision or have blurred vision.</li></ul>	<b>notice any of these serious side effects.</b>

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

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

**Other side effects not listed here may 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.**

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What BUDAMAX contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• <b>64 mg Budesonide per dose</b></li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• disodium edetate</li><li>• potassium sorbate (E202)</li><li>• glucose</li><li>• dispersible cellulose</li><li>• polysorbate 80 (E433)</li><li>• purified water</li><li>• hydrochloric acid (E507) may have been added to adjust the pH of the solution.</li></ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"><li>• potassium sorbate</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What BUDAMAX looks like

Budamax comes in a brown glass bottle containing approximately 50 (sample pack) or 120 doses, with metered pump spray equipment and nasal adaptor. The

120 dose bottle is available as a 1 (120 doses) or 2 bottle (240 dose) pack (2 bottles).

Budamax Aqueous 64 micrograms Nasal Spray - AUST R 75659

Budamax Aqueous 32 micrograms Nasal Spray- AUST R 75657

### **Who distributes BUDAMAX**

Johnson & Johnson Pacific

AUSTRALIA · NEW ZEALAND

45 Jones Street, Ultimo NSW 2007

\* Registered Trademark

Consumer Care Centre

Australia: 1800 029 979

New Zealand: 0800 446 147

Overseas Customers: +61 2 8260 8366

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