

# AXOTIDE ACCUHALER, AXOTIDE JUNIOR ACCUHALER

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## 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.

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### 1. Why am I using Axotide Accuhaler?

AXOTIDE ACCUHALER contains the active ingredient Fluticasone propionate. AXOTIDE ACCUHALERS are used reduce the swelling and irritation in the walls of the small air passages in your lungs.

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

### 2. What should I know before I use Axotide Accuhaler?

Do not use if you have ever had an allergic reaction to AXOTIDE ACCUHALER or any of the ingredients listed at the in 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 Axotide Accuhaler?](#) in the full CMI.

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

Some medicines may interfere with AXOTIDE ACCUHALER 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 Axotide Accuhaler?**

- **For adults:** The usual dose is in the range of 100 to 1000 micrograms twice daily.
- **For children:** The usual dose is 100 micrograms twice daily.
- More instructions can be found in Section [4. How do I use Axotide Accuhaler?](#) in the full CMI.

### **5. What should I know while using Axotide Accuhaler?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you</li></ul>
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	<p>are using AXOTIDE ACCUHALER.</p> <ul style="list-style-type: none"> <li>• Tell your doctor if you become pregnant or are trying to become pregnant or breastfeeding.</li> <li>• Tell your doctor if you experience a change in your vision.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop using AXOTIDE ACCUHALER or change the dose without first checking with your doctor.</li> <li>• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.</li> <li>• Do not use AXOTIDE ACCUHALER to treat any other complaints unless your doctor says to.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• AXOTIDE ACCUHALER is unlikely to affect your ability to drive or operate machinery.</li> </ul>

### Looking after your medicine

- Store your AXOTIDE ACCUHALER below 30°C, protected from direct sunlight.
- Do not freeze.

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

## 6. Are there any side effects?

If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. AXOTIDE ACCUHALER can cause eye problems (eg. cataract, glaucoma), loss of bone density, increase in the amount of sugar (glucose) in your blood and allergic reactions which may be severe. **If you develop symptoms of an allergic reaction, call your doctor straight away or go straight to the Emergency Department at your nearest hospital.** 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.

# AXOTIDE ACCUHALER

Active ingredient: *Fluticasone propionate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using AXOTIDE ACCUHALER. **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 AXOTIDE ACCUHALER.**

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

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

## 1. Why am I using AXOTIDE ACCUHALER?

**AXOTIDE ACCUHALER contains a steroid called fluticasone propionate which, reduces the swelling and irritation in the walls of the small air passages in your lungs.**

AXOTIDE ACCUHALER contains the type of asthma medicine known as a 'preventer'. It does not give immediate relief from an asthma attack and may take up to a week to start to work. If your shortness of breath or wheeze does not get better after 7 days, tell your doctor. When used every day, your AXOTIDE ACCUHALER helps to ease breathing problems and prevent asthma attacks.

This medicine is only one part of a general plan to help you manage your asthma. You should discuss this plan with your doctor. You may also be using a 'reliever puffer'. Keep using it according to your doctor's advice. Ask your doctor to check your treatment regularly.

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

The medicine in AXOTIDE ACCUHALER is not addictive.

## **2. What should I know before I use AXOTIDE ACCUHALER?**

### **Warnings**

#### **Do not use AXOTIDE ACCUHALER if:**

- you are allergic to fluticasone propionate, or any of the ingredients listed at the end of this leaflet.
- you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should. It is important that asthma is managed well during

pregnancy and you should not stop your medicine without asking your doctor.

- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

### **Check with your doctor if you:**

- have any other medical conditions.
- are taking other steroid medicines by mouth or inhalation. If you are already taking steroid tablets, you should carry a warning card about needing extra oral steroids during periods of stress e.g. worsening asthma attacks, chest infections, surgery, trauma and other major illnesses occurring at the same time.
- have ever had to stop taking other asthma medicines.
- have tuberculosis (TB) of the lung or other long term lung infection.
- are allergic to foods, dyes, preservatives or any other medicines.

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 may interfere with AXOTIDE ACCUHALER and affect how it works.**

For example, medicines like ketoconazole, used to treat fungal infection, and ritonavir used to treat HIV infection, may affect how AXOTIDE ACCUHALER works. If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

#### **Other types of asthma medicines**

Your AXOTIDE ACCUHALER contains the kind of asthma medicine known as a 'preventer'. There are other types of inhalers that relieve your breathing problems when you are wheezing or your chest is tight. These medicines are called 'relievers'. Your doctor may tell you to use a 'reliever' in addition to your AXOTIDE ACCUHALER.

### **4. How do I use AXOTIDE ACCUHALER?**

#### **How to use it**

Remember that the medicine in your AXOTIDE ACCUHALER is taken by inhalation only.

You will find the instructions on how to use your AXOTIDE ACCUHALER in the pack. Follow the instructions carefully.

## How much to use

The pharmacist's label will usually tell you how many inhalations and how often to use your AXOTIDE ACCUHALER. If you are not sure, ask your doctor or pharmacist.

- **For adults:** The usual dose is in the range of 100 to 1000 micrograms twice daily.
- **For children:** The usual dose is 100 micrograms twice daily.
- Your doctor will decide what dose you should take, how often you should take it, and what strength of AXOTIDE ACCUHALER you should use.
- You should visit your doctor or pharmacist regularly to check that you are using your AXOTIDE ACCUHALER in the right way. If you are not breathing the medicine in correctly, the medicine may not be helping you as much as it could.

### When not to use it

Do not use your AXOTIDE ACCUHALER to treat a sudden attack of breathlessness. You will need a different kind of medicine called a 'reliever' which your doctor will have told you to take.

## **How long to use AXOTIDE ACCUHALER**

You must use your AXOTIDE ACCUHALER every day. Do not stop using it, even if you feel better, unless your doctor tells you.

## **If you forget to use AXOTIDE ACCUHALER**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, use the product as soon as you remember, then go back to using the product as you would normally**

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

**If you become wheezy or feel tight in the chest before the next dose is due, use a 'reliever puffer' in the usual way. You should get relief from your 'reliever puffer' within a few minutes**

## **If you use too much AXOTIDE ACCUHALER**

If you think that you have used too much AXOTIDE ACCUHALER, 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 AXOTIDE ACCUHALER?**

### **Things you should do**

- Tell your doctor or pharmacist that you are using AXOTIDE ACCUHALER if you are about to be started on any new medicines.
- If you have to go into hospital for an operation, take your AXOTIDE ACCUHALER with you and tell the doctor what medicine(s) you are taking.
- Tell your doctor if you become pregnant or are trying to become pregnant.
- Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.
- Tell your doctor if you experience a change in your vision.
- Use AXOTIDE ACCUHALER only in your nose.  
Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

### **Call your doctor straight away if you:**

- think you may be having an allergic reaction

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

## Things you should not do

- Do not stop using AXOTIDE ACCUHALER or change the dose without first checking with your doctor.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use AXOTIDE ACCUHALER to treat any other complaints unless your doctor says to.
- Do not stop using this medicine suddenly.

Taking high doses of steroids for a long time this could affect the adrenal glands, which make the body's own steroid. Your doctor may do tests to check how the adrenal glands are working. Your doctor will be able to answer any questions you may have.

It is important that all doctors treating you are aware that you are on inhaled steroids. If your body is stressed by, for example, severe infection, surgical operation, an accident etc, you may need steroid tablets or injections for a time.

## Driving or using machines

AXOTIDE ACCUHALER is unlikely to affect your ability to drive.

## Looking after your medicine

- **Store your AXOTIDE ACCUHALER upright, at below 30°C.**
- **Protect the drops from direct sunlight.**
- **Do not freeze.**

**Do not store, or any other medicine, in a bathroom or near a sink.**

- **Do not leave in the car or on window sills.**

Heat and dampness can destroy some medicines.

Store AXOTIDE ACCUHALER in the foil overwrap until you are ready to use it for the first time. Once opened the foil overwrap should be discarded.

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

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

Condensation may form on the inside of the foil pack during storage, but it is not a cause for concern.

## **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.

## **If your AXOTIDE ACCUHALER does not have the usual effect**

If your chest condition gets worse, tell your doctor. Your doctor may tell you to take extra puffs of your AXOTIDE ACCUHALER or add another medicine (such as a 'reliever puffer') to your treatment.

**IMPORTANT: IF YOUR BREATHING SUDDENLY BECOMES MORE DIFFICULT JUST AFTER YOU HAVE USED YOUR AXOTIDE ACCUHALER, YOU**

## **WILL NEED TO USE A 'RELIEVER PUFFER' AND TELL YOUR DOCTOR IMMEDIATELY.**

Tell your doctor as soon as possible if:

- your 'reliever puffer' does not help your breathing as much as usual.
- the effect of your 'reliever puffer' does not last as long as usual.
- you need more puffs of your 'reliever puffer' than usual to get relief.

## **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, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• sneezing</li><li>• irritation or dryness in the nose or throat</li><li>• bad taste or smell</li><li>• nose bleed</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● a sore throat or tongue. This may be due to 'thrush' (candida infection)*</li> <li>● hoarseness or throat irritation*</li> <li>● rounded face</li> <li>● disturbed sleep or notice increased irritability (mainly in children).</li> </ul> <p>* For these, it may be helpful to rinse your mouth with water and spit it out after using your AXOTIDE ACCUHALER. Your doctor may prescribe treatment for the 'thrush' in your mouth while you continue to use your AXOTIDE ACCUHALER.</p>	

### **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Eyes</b></p> <ul style="list-style-type: none"> <li>● cloudy lens in the eye (cataract), increased</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>pressure of the eye that causes problems with vision (glaucoma). These eye problems occurred in people who used AXOTIDE ACCUHALER for a long time.</p> <p><b>Allergic Reaction:</b></p> <ul style="list-style-type: none"> <li>● wheezing</li> <li>● swelling of the lips/ mouth</li> <li>● difficulty in breathing</li> <li>● hay fever</li> <li>● lumpy rash ("hives")</li> <li>● fainting</li> </ul>	<p><b>nearest hospital if you notice any of these serious side effects.</b></p>

**There may be an increase in the amount of sugar (glucose) in your blood. If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetes treatment may be required.**

It is possible that some people, particularly those taking higher doses of AXOTIDE ACCUHALER for a long time, may rarely suffer from the following side effects:

- rounded face
- loss of bone density

- eye problems (eg. cataract, glaucoma)
- slowing of growth in children. It is unclear what, if any, difference this makes to their final height
- Soreness in the food pipe.

**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.

## **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 AXOTIDE ACCUHALER contains**

<b>Active ingredient (main ingredient)</b>	fluticasone propionate
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<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate powder
<b>Potential allergens</b>	Milk protein

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

## **What AXOTIDE ACCUHALER looks like**

The AXOTIDE ACCUHALER is a plastic device which contains a foil strip inside. The foil strip has pockets (called blisters) which contain your medicine. The AXOTIDE ACCUHALER is packaged within a foil overwrap. The plastic device is labelled, "AXOTIDE ACCUHALER". Each device contains 60 blisters. Your AXOTIDE ACCUHALER has a dose counter which tells you how many doses are left. To let you know when you have reached the last five doses, the numbers appear in red.

JUNIOR ACCUHALER 100 micrograms of fluticasone propionate in a blister, 60 doses (AUST R 267493)

ACCUHALER 250 micrograms of fluticasone propionate in a blister, 60 doses (AUST R 267491)

## **Who distributes Axotide Accuhaler**

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria 3067

Australia

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