

AXOTIDE CFC-FREE INHALER and JUNIOR CFC-FREE INHALER ['PUFFER']

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 AXOTIDE PUFFER?

AXOTIDE CFC-FREE INHALER and JUNIOR CFC-FREE INHALER ['PUFFER'] contains the active ingredient fluticasone propionate. AXOTIDE CFC-FREE INHALER and JUNIOR CFC-FREE INHALER helps to ease breathing problems and prevent asthma attacks.

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

2. What should I know before I use AXOTIDE PUFFER?

Do not use if you have ever had an allergic reaction to Axotide puffer 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 Axotide puffer?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Axotide puffer 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 PUFFER?

- **For adults:** The usual dose is in the range of 100 to 1000 micrograms twice daily.
- **For children from 1 to 16 years of age:** The usual dose is in the range of 50 to 100 micrograms twice daily.
- More instructions can be found in Section [4. How do I use Axotide puffer?](#) in the full CMI.

5. What should I know while using AXOTIDE PUFFER?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Axotide puffer.• Tell your doctor or pharmacist that you are using an Axotide puffer if you are about to be started on any new medicines.• If you have to go into hospital for an operation, take your Axotide puffer 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.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.• Do not use your Axotide puffer to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• Axotide puffers generally do not cause any problems with your ability to drive a car or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Keep your Axotide puffer away from heat (store below 30°C), and bright sunlight.• Keep your Axotide puffer away from frost. Do not put it in the refrigerator.• Do not leave it in the car or on window sills

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

6. Are there any side effects?

The commonly reported side-effects are a sore throat or tongue and hoarseness or throat irritation, and serious side effects of an allergic reaction usually include wheezing, swelling of the lips/mouth, lumpy rash ("hives") and fainting. 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 CFC-FREE INHALER and JUNIOR CFC-FREE INHALER ['PUFFER']

Active ingredient(s): *fluticasone propionate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using AXOTIDE CFC-FREE INHALER and JUNIOR CFC-FREE INHALER ['PUFFER']. **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 CFC-FREE INHALER and JUNIOR CFC-FREE INHALER ['PUFFER'].**

Where to find information in this leaflet:

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

1. Why am I using AXOTIDE PUFFER?

You may know your Inhaler better as a 'puffer'. AXOTIDE PUFFER contains the active ingredient *fluticasone propionate*. This medicine belongs to a group of medicines known as corticosteroids, frequently called 'steroids'. They are not 'anabolic steroids' which are the steroids sometimes misused by athletes.

Your Axotide puffer provides a measured amount of steroid for you to breathe into your lungs. By using your Axotide puffer regularly every day, the medicine reduces the swelling and irritation in the walls of the small air passages in your lungs. Your Axotide puffer 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 puffer 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 quick acting medicine such as Ventolin. 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 an Axotide puffer has been prescribed for you.

The medicine in Axotide puffers is not addictive.

2. What should I know before I use AXOTIDE PUFFER?

Warnings

Do not use AXOTIDE PUFFER if:

- you are allergic to fluticasone propionate or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may be mild or severe. They usually

include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

- 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.
- always check the ingredients to make sure you can use this medicine.

Check with your doctor if:

- you 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 eg. worsening asthma attacks, chest infections, surgery, trauma and other major illnesses occurring at the same time. Discuss this with your doctor.
- you have ever had to stop taking other asthma medicines.
- you have tuberculosis (TB) of the lung or other long term lung infection.
- you 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.

Your doctor will discuss the risks and benefits of using your Axotide puffer if you are pregnant or breastfeeding.

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 CFC-FREE INHALER and JUNIOR CFC-FREE INHALER ['PUFFER'] 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 puffer works. If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

4. How do I use AXOTIDE PUFFER?

How to use it

Remember that the medicine in your Axotide puffer is taken by inhalation only.

You will find the instructions on how to use your Axotide puffer on the leaflet 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 puffer. 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 from 1 to 16 years of age: The usual dose is in the range of 50 to 100 micrograms twice daily.

Your doctor will decide what dose you should take, how often you should take it, and what strength of Axotide puffer you should use.

You should visit your doctor or pharmacist regularly to check that you are using your Axotide puffer 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.

For children under 8 years of age, the medicine is usually breathed in using something called a 'spacer'. Your doctor or pharmacist will explain to you what this is and how to use it.

If you find it difficult to breathe in and press your Axotide Inhaler at the same time, talk to your doctor or pharmacist. It may be better for you to use something called a 'spacer' with your Axotide puffer. Your doctor or pharmacist will explain to you what this is and how to use it.

If you change the make of spacer you use this may alter the amount of drug delivered to the lungs. You should let your doctor know if your asthma symptoms worsen.

If you have any questions about using a spacer, ask your doctor or pharmacist.

When to not use it

Do not use your Axotide puffer 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 PUFFER

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

If you forget to use AXOTIDE PUFFER

You must use your Axotide puffer every day. If you forget to take a dose, do not worry. Just take the next dose when it is due.

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 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 PUFFER

If you think that you have used too much Axotide puffer, 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 PUFFER?

Things you should do

- Tell your doctor or pharmacist that you are using an Axotide puffer if you are about to be started on any new medicines.
- If you have to go into hospital for an operation, take your Axotide puffer 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 taken your medicine exactly as prescribed.
- Otherwise, your doctor may think that your medicine 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 PUFFER.

Things you should not do

- Do not stop using your Axotide puffer 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 your Axotide puffer to treat any other complaints unless your doctor says to.

If your AXOTIDE PUFFER 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 puffer 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 puffer, 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.

Driving or using machines

AXOTIDE PUFFERS generally do not cause any problems with your ability to drive a car or operate machinery.

Looking after your medicine

Straight after use, replace mouthpiece cover firmly and click it into position. Do not use excessive force.

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

- **Keep your Axotide puffer away from frost. Do not put it in the refrigerator.**
- **Keep your Axotide puffer away from heat (store below 30°C, and bright sunlight).**

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.

Heat can destroy some medicines.

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.

If your Axotide puffer becomes very cold, it may not work properly. To warm it, pull out the metal can from its plastic holder and warm it in your hand for a few minutes. Do not warm the can in any other way. Push the can firmly back into its holder before using.

Getting rid of any unwanted medicine

If your doctor tells you to stop using your Axotide puffer, or the product has passed its expiry date, ask your pharmacist what to do with any Axotide puffer left over.

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.

WARNING: The metal can is pressurised. Do not burn it or puncture it, even when it is empty.

You can recycle the plastic holder and cap of your Axotide puffer with other plastic things.

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.

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

Less serious side effects

Less serious side effects	What to do
Local: <ul style="list-style-type: none"> • a sore throat or tongue. This may be due to 'thrush' (candida infection) * 	Speak to your doctor if you have any of these less serious side

Less serious side effects	What to do
<ul style="list-style-type: none"> • hoarseness or throat irritation* • soreness in the oesophagus <p>For these, it may be helpful to rinse your mouth with water and spit it out after using your Axotide puffer. Your doctor may prescribe treatment for the 'thrush' in your mouth while you continue to use your Axotide puffer.</p> <p>Other:</p> <ul style="list-style-type: none"> • feeling anxious • disturbed sleep • loss of bone density • rounded face • increased irritability (mainly in children) • slowing of growth in children. It is unclear what, if any, difference this makes to their final height <p>Please note 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.</p>	effects and they worry you.

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:

- treatment with your Axotide puffer should not be stopped suddenly
- 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.

If you feel unwell in any other way or have any symptoms that you do not understand, you should ask your doctor immediately.

Serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> • wheezing, • swelling of the lips/mouth, tongue or throat • difficulty in breathing, • hay fever, • lumpy rash ("hives") • fainting <p>Eye disorders:</p> <ul style="list-style-type: none"> • eye problems (eg. cataract, glaucoma) 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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.

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. 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 puffer contains

Active ingredient (main ingredient)	fluticasone propionate
Other ingredients (inactive ingredients)	norflurane

Axotide puffers contain the medicine called fluticasone propionate. They are available in the following strengths:

Axotide Junior (CFC-free) Inhaler, containing 50 micrograms of fluticasone propionate in each puff.

Axotide (CFC-free) Inhaler, containing 125 micrograms of fluticasone propionate in each puff.

Axotide (CFC-free) Inhaler, containing 250 micrograms of fluticasone propionate in each puff.

Cans containing 120 puffs are available.

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

What Axotide puffer looks like

An Axotide puffer consists of a plastic holder which contains a small metal can. The holder has a mouthpiece which is covered by a cap.

- Junior (CFC-Free) Inhaler, 50micrograms per metered dose, 120 doses, AUST R 267496
- (CFC-Free) Inhaler, 125 micrograms per metered dose, 120 doses, AUST R 267494
- (CFC-Free) Inhaler, 250 micrograms per metered dose, 120 doses, AUST R 267495.

Who distributes Axotide puffer

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

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