

# FLIXOTIDE ACCUHALER, FLIXOTIDE 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 FLIXOTIDE ACCUHALER?

FLIXOTIDE ACCUHALER contains the active ingredient fluticasone propionate. FLIXOTIDE ACCUHALER is used to 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 FLIXOTIDE ACCUHALER?](#) in the full CMI.

### 2. What should I know before I use FLIXOTIDE ACCUHALER?

Do not use if you have ever had an allergic reaction to fluticasone propionate 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 FLIXOTIDE ACCUHALER?](#) in the full CMI.

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

Some medicines may interfere with FLIXOTIDE 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 FLIXOTIDE ACCUHALER?**

- For adults: The usual dose is in the range of 100 to 1000 micrograms twice daily.
- For children: 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 FLIXOTIDE ACCUHALER?](#) in the full CMI.

### **5. What should I know while using FLIXOTIDE ACCUHALER?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor or pharmacist you</li></ul>
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	<p>visit that you are using FLIXOTIDE ACCUHALER.</p> <ul style="list-style-type: none"> <li>• Tell your doctor immediately, if you become or intend to become pregnant or are 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 FLIXOTIDE 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 FLIXOTIDE 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>• FLIXOTIDE ACCUHALER is unlikely to affect your ability</li> </ul>

	to drive or operate machinery.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store FLIXOTIDE ACCUHALER below 30°C in a dry place away from heat.</li> <li>• Store in the foil overwrap until you are ready to use it for the first time.</li> </ul>

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

## 6. Are there any side effects?

Less serious side effects which have been reported include a sore throat or tongue, hoarseness or throat irritation, soreness in the oesophagus, rounded face, slowing of growth in children, loss of bone density, anxiety, disturbed sleep, increased irritability (mainly in children) or hyperglycaemia. Serious side effects include eye problems, effects on adrenal glands or allergic reaction.

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.

# FLIXOTIDE ACCUHALER & FLIXOTIDE JUNIOR ACCUHALER

**Active ingredient:** *fluticasone propionate*

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## **Consumer Medicine Information (CMI)**

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

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

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

# **1. Why am I using FLIXOTIDE ACCUHALER?**

**FLIXOTIDE ACCUHALER contains the active ingredient fluticasone propionate.** Fluticasone propionate 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. FLIXOTIDE ACCUHALER provides a measured amount of steroid for you to breathe into your lungs.

**FLIXOTIDE ACCUHALER reduces the swelling and irritation in the walls of the small air passages in your lungs, if used regularly every day.**

FLIXOTIDE 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 FLIXOTIDE 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.

**FLIXOTIDE ACCUHALER should not be used to relieve a sudden attack of breathlessness or wheezing. If you get this sort of attack, you will need**

**a different kind of medicine called a 'reliever' which your doctor will have told you to take.**

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

This medicine is not addictive.

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

### **Warnings**

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

- you are allergic (hypersensitive) to fluticasone propionate, or any of the ingredients listed at the end of this leaflet.
- you are allergic (hypersensitive) to lactose or milk protein.
- the expiry date (EXP) printed on the pack has passed or if 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 allergic to foods, dyes, preservatives or any other medicines.
- are not sure whether you should be using FLIXOTIDE ACCUHALER.

- have any other medical conditions.
- have ever had to stop taking other asthma medicines.
- have tuberculosis (TB) of the lung or other long term lung infection.

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.

It is important that your asthma is managed well during your pregnancy and you should not stop your medicine without asking your doctor.

Your doctor will discuss the risks and benefits of using FLIXOTIDE ACCUHALER 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 FLIXOTIDE ACCUHALER and affect how it works.**



### **These medicines include:**

- ketoconazole, to treat fungal infections.
- ritonavir, to treat HIV infection.
- 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.

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

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

### **How to use FLIXOTIDE ACCUHALER**

Always use FLIXOTIDE ACCUHALER exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

- The medicine in FLIXOTIDE ACCUHALER is taken by inhalation only.
- Rinse your mouth out with water without swallowing after you have used FLIXOTIDE ACCUHALER if possible. This will make it less likely that you will develop a sore mouth or throat as side effects. Your doctor may prescribe treatment if you experience 'oral

thrush' while you continue to use your FLIXOTIDE ACCUHALER.

- You will find the instructions on how to use your FLIXOTIDE 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 FLIXOTIDE ACCUHALER. If you are not sure, ask your doctor or pharmacist.

### **Adults:**

- The usual dose is in the range of 100 to 1000 micrograms twice daily.

### **Children:**

- 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 FLIXOTIDE ACCUHALER you should use.

You should visit your doctor or pharmacist regularly to check that you are using your FLIXOTIDE 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 to use FLIXOTIDE ACCUHALER**

- Use FLIXOTIDE ACCUHALER every day. Do not stop using it, even if you feel better, unless your doctor tells you.

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

If you forget to take a dose, do not worry. Just take the next dose when it is due.

**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 the 'reliever puffer' within a few minutes.

## **If you use too much FLIXOTIDE ACCUHALER (overdose)**

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

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia**), 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 FLIXOTIDE ACCUHALER?**

### **Things you should do**

- Remind any doctor or pharmacist you visit that you are using FLIXOTIDE ACCUHALER. 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.
- If you are about to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

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

- become pregnant or are trying to become pregnant.
- experience a change in your vision.
- have not taken your medicine exactly as prescribed. Otherwise your doctor may think that your medicine was not effective and change your treatment unnecessarily.
- notice your chest condition gets worse. Your doctor may tell you to take extra puffs of your FLIXOTIDE ACCUHALER or add another medicine (such as a 'reliever puffer') to your treatment.

- notice your breathing suddenly becomes more difficult just after you have used your FLIXOTIDE ACCUHALER. You will need to use a 'reliever puffer'.
- notice your 'reliever puffer' does not help your breathing as much as usual.
- notice the effect of your 'reliever puffer' does not last as long as usual.
- need more puffs of your 'reliever puffer' than usual to get relief.

## **Things you should not do**

- Do not stop using FLIXOTIDE 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 FLIXOTIDE ACCUHALER to treat any other complaints unless your doctor says to.

## **Driving or using machines**

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

FLIXOTIDE ACCUHALER generally does not cause any problems with your ability to drive a car or operate machinery.

## Looking after your medicine

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

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 where the temperature stays below 30°C.

### **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.**

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

## 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 or if the packaging is torn or shows signs of tampering.

## **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 they are connected with the medicine or are not listed in this leaflet.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

## **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>• disturbed sleep.</li> <li>• increased irritability (mainly in children).</li> <li>• anxiety.</li> </ul> <p><b>Respiratory, thoracic and mediastinal disorders:</b></p> <ul style="list-style-type: none"> <li>• hoarseness or throat irritation.</li> <li>• soreness in oesophagus.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>
<p><b>Less serious side effects that require medical intervention. Please consult your doctor if</b></p>	<p><b>Contact your doctor if you experience any of these less serious side effects.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>you experience any of the following:</b></p> <ul style="list-style-type: none"> <li>• sore throat or tongue. This may be due to 'oral thrush' (candida infection).</li> <li>• rounded face.</li> <li>• loss of bone density.</li> <li>• slowing of growth in children. It is unclear what, if any, difference this makes to their final height.</li> <li>• increase in blood sugar (hyperglycaemia). If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetes treatment may be required.</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Immune system disorders and allergic reactions:</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency</b></p>



Serious side effects	What to do
<ul style="list-style-type: none"> <li>• If you have any of the following symptoms after using FLIXOTIDE ACCUHALER, stop using this medicine and tell your doctor immediately.</li> <li>• Symptoms of an allergic reaction usually include some or all of the following: <ul style="list-style-type: none"> <li>◦ wheezing</li> <li>◦ difficulty breathing</li> <li>◦ swelling of the lips/ mouth, tongue or throat</li> <li>◦ hay fever</li> <li>◦ lumpy rash ("hives")</li> <li>◦ fainting</li> </ul> </li> </ul> <p><b>Eye problems:</b></p> <ul style="list-style-type: none"> <li>• cataracts.</li> <li>• glaucoma.</li> </ul> <p><b>Hormonal system:</b></p> <ul style="list-style-type: none"> <li>• Effects on the adrenal glands. <ul style="list-style-type: none"> <li>◦ Taking high doses of steroids for a long time could affect</li> </ul> </li> </ul>	<p><b>Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
the adrenal glands, which make the body's own steroid. Your doctor may do tests to check how the adrenal glands are working.	

**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 FLIXOTIDE ACCUHALER contains

<b>Active ingredient</b>	Fluticasone propionate
<b>Other ingredients</b>	Lactose monohydrate
<b>Potential allergens</b>	Milk protein

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

## What FLIXOTIDE ACCUHALER looks like

FLIXOTIDE ACCUHALER is a plastic device which contains a foil strip inside. The foil strip has pockets (called blisters) which contain your medicine. The FLIXOTIDE ACCUHALER is packaged within a foil overwrap. The plastic device is labelled, "FLIXOTIDE ACCUHALER".

Each device contains 60 blisters. FLIXOTIDE 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.

### **FLIXOTIDE ACCUHALER is available in three strengths:**

FLIXOTIDE JUNIOR ACCUHALER 100 micrograms of fluticasone propionate in a blister (AUST R 58439).

FLIXOTIDE ACCUHALER 250 micrograms of fluticasone propionate in a blister (AUST R 58438).

FLIXOTIDE ACCUHALER 500 micrograms of fluticasone propionate in a blister (AUST R 58437).

## **Who distributes FLIXOTIDE ACCUHALER**

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

[www.gsk.com.au](http://www.gsk.com.au)

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