

FLIXOTIDE CFC-FREE INHALER, FLIXOTIDE JUNIOR CFC-FREE INHALER

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 FLIXOTIDE INHALER?

FLIXOTIDE INHALER contains the active ingredient fluticasone propionate. FLIXOTIDE INHALER 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 INHALER?](#) in the full CMI.

2. What should I know before I use FLIXOTIDE INHALER?

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 INHALER?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FLIXOTIDE INHALER 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 INHALER?

- For adults and children over 16 years: the usual dose is in the range of 100 to 1000 micrograms twice daily.
- For children from 1 to 16 years: 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 INHALER?](#) in the full CMI.

5. What should I know while using FLIXOTIDE INHALER?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor or pharmacist you visit

	<p>that you are using FLIXOTIDE INHALER.</p> <ul style="list-style-type: none"> • Tell your doctor immediately, if you become or intend to become pregnant. • Tell your doctor if you experience a change in your vision.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using FLIXOTIDE INHALER 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 INHALER to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none"> • FLIXOTIDE INHALER is unlikely to affect your ability to drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none"> • Store FLIXOTIDE INHALER below 30°C in

	<p>a dry place away from heat and frost.</p> <ul style="list-style-type: none"> • Do not put it in the refrigerator.
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For more information, see Section [5. What should I know while using FLIXOTIDE INHALER?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects which have been reported include a sore throat or tongue, and hoarseness or throat irritation, soreness in the oesophagus, rounded face, loss of bone density, slowing of growth in children, 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 CFC-FREE INHALER & FLIXOTIDE JUNIOR CFC-FREE INHALER

Active ingredient: *fluticasone propionate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using FLIXOTIDE INHALER?

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

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

You may know your inhaler better as a 'puffer'.

FLIXOTIDE INHALER 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 INHALER 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 INHALER 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 INHALER has been prescribed for you.

This medicine is not addictive.

2. What should I know before I use FLIXOTIDE INHALER?

Warnings

Do not use FLIXOTIDE INHALER if:

- you are allergic (hypersensitive) to fluticasone propionate, or any of the ingredients listed at the end of this leaflet.
- 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 INHALER.
- 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 asthma is managed well during pregnancy and you should not stop your medicine without asking your doctor.

Your doctor will discuss the risks and benefits of using FLIXOTIDE INHALER 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 INHALER 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 INHALER.

4. How do I use FLIXOTIDE INHALER?

How to use FLIXOTIDE INHALER

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

The medicine in FLIXOTIDE INHALER is taken by inhalation only.

You will find instructions on how to use your FLIXOTIDE INHALER in the pack. Follow the instructions carefully.

You should visit your doctor regularly to check that you are using your FLIXOTIDE INHALER the right way.

If you are not breathing the medicine in correctly, the medicine may not be helping you as much as it could.

- If your FLIXOTIDE INHALER 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.
- For children under 8 years of age, the medicine is usually breathed in using something called a 'spacer'.

Your doctor will explain to you what this is and how to use it.

- If you find it difficult to breathe in and press your FLIXOTIDE INHALER at the same time, talk to your doctor. It may be better to use a spacer with your FLIXOTIDE INHALER. Your doctor 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 symptoms worsen.
- Rinse your mouth out with water without swallowing after you have used the inhaler 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 FLIXOTIDE INHALER.

How much to use

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

Adults and children over 16 years:

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

Children (from 1 to 16 years):

- 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 use it, and what strength of FLIXOTIDE INHALER you should use.

When to use FLIXOTIDE INHALER

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

If you forget to use FLIXOTIDE INHALER

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 your 'reliever puffer' within a few minutes.

If you use too much FLIXOTIDE INHALER (overdose)

If you think that you have used too much FLIXOTIDE INHALER, 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 INHALER?

Things you should do

- Remind any doctor or pharmacist you visit that you are using FLIXOTIDE INHALER. 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 INHALER or add another medicine (such as a 'reliever puffer') to your treatment.

- notice if your breathing suddenly becomes more difficult just after you have used your FLIXOTIDE INHALER. 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 INHALER, 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 INHALER 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 INHALER affects you.

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

Looking after your medicine

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

- If your FLIXOTIDE INHALER 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.

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, frost, 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, or
- in the refrigerator.

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.

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 FLIXOTIDE INHALER with other hard plastics.

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 FLIXOTIDE INHALER for a long time, may rarely suffer from the following side effects:

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

Less serious side effects

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

Less serious side effects	What to do
<ul style="list-style-type: none"> • soreness in the oesophagus. 	
<p>Less serious side effects that require medical intervention. Please consult your doctor if you experience any of the following:</p> <ul style="list-style-type: none"> • sore throat or tongue. This may be due to 'oral thrush' (candida infection). • rounded face. • loss of bone density. • slowing of growth in children. It is unclear what, if any, difference this makes to their final height. • 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. 	<p>Contact your doctor if you experience any of these less serious side effects.</p>

Serious side effects

Serious side effects	What to do
<p>Immune system disorders and allergic reactions:</p> <ul style="list-style-type: none"> ● If you have any of the following symptoms after using FLIXOTIDE INHALER, stop using this medicine and tell your doctor immediately. ● Symptoms of an allergic reaction include some or all of the following: <ul style="list-style-type: none"> ○ wheezing ○ difficulty breathing ○ swelling of the lips/ mouth, tongue or throat ○ hay fever ○ lumpy rash ("hives") ○ fainting <p>Eye disorders:</p> <ul style="list-style-type: none"> ● cataract. ● glaucoma. <p>Hormonal system:</p>	<p>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.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • effects on the adrenal glands <ul style="list-style-type: none"> ◦ Taking high doses of steroids for a long time 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. 	

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 FLIXOTIDE INHALER contains

Active ingredient	Fluticasone propionate
Other ingredients	Norflurane

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

What FLIXOTIDE INHALER looks like

FLIXOTIDE INHALER consists of a plastic holder which contains a small metal can. The holder has a mouthpiece which is covered by a cap.

FLIXOTIDE INHALER is available in the following strengths:

- FLIXOTIDE JUNIOR (CFC-FREE) INHALER
fluticasone propionate 50 microgram/actuation
inhalation-pressurised aerosol can-metered dose
(AUST R 76865)
- FLIXOTIDE CFC-Free fluticasone propionate 125
microgram/dose inhalation metered dose aerosol can
(AUST R 63447)

- FLIXOTIDE CFC-Free fluticasone propionate 250 microgram/dose inhalation metered dose aerosol can (AUST R 63448)

Cans containing either 60 puffs or 120 puffs are available.

Not all pack sizes may be distributed in Australia

Who distributes FLIXOTIDE INHALER

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

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