

FLUTICASONE SALMETEROL CIPHALER 500/50

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 FLUTICASONE SALMETEROL CIPHALER 500/50?

FLUTICASONE SALMETEROL CIPHALER 500/50 contains the active ingredients fluticasone propionate and salmeterol (as xinafoate). FLUTICASONE SALMETEROL CIPHALER 500/50 is used to help with asthma and chronic obstructive pulmonary disease (COPD) in people who need regular treatment.

For more information, see Section [1. Why am I using FLUTICASONE SALMETEROL CIPHALER 500/50?](#) in the full CMI.

2. What should I know before I use FLUTICASONE SALMETEROL CIPHALER 500/50?

Do not use if you have ever had an allergic reaction to any medicine containing fluticasone propionate or salmeterol (as xinafoate) or lactose monohydrate 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 FLUTICASONE SALMETEROL CIPHALER 500/50?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FLUTICASONE SALMETEROL CIPHALER 500/50 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 FLUTICASONE SALMETEROL CIPHALER 500/50?

- Follow dosage directions given to you by your doctor or pharmacist and continue taking it for as long as your doctor tells you.
 - FLUTICASONE SALMETEROL CIPHALER 500/50 should be inhaled into your lungs through the mouth, through the inhaler.
- More instructions can be found in Section [4. How do I use FLUTICASONE SALMETEROL CIPHALER 500/50?](#) in the full CMI.

5. What should I know while using FLUTICASONE SALMETEROL CIPHALER 500/50?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using FLUTICASONE SALMETEROL CIPHALER 500/50.If you are going to have surgery, tell the surgeon or anesthetist that you are taking this medicine.Tell your doctor if you become, or are trying to become, pregnant.Tell your doctor if you are using FLUTICASONE SALMETEROL CIPHALER 500/50, if you have any blood tests.Contact your doctor if you experience a change in your vision.Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine suddenly or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">This medicine is not expected to affect your ability to drive a car or operate machinery. It is prudent to be careful driving or operating machinery until you know how FLUTICASONE SALMETEROL CIPHALER 500/50 affects you.
Looking after your medicine	<ul style="list-style-type: none">Keep FLUTICASONE SALMETEROL CIPHALER 500/50 in a dry place where the temperature stays below 30°C away from direct heat or sunlight.Keep it where children cannot reach it.

For more information, see Section [5. What should I know while using FLUTICASONE SALMETEROL CIPHALER 500/50?](#) in the full CMI.

6. Are there any side effects?

The following common side effects may occur when taking FLUTICASONE SALMETEROL CIPHALER 500/50; soreness in the mouth, throat or tongue, hoarseness, headache, muscle cramps, pain in joints, increase in heart rate, pneumonia. If your breathing or wheezing gets worse straight after using FLUTICASONE SALMETEROL CIPHALER 500/50, stop using it immediately and tell your doctor as soon as possible.

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.

FLUTICASONE SALMETEROL CIPHALER

500/50

Active ingredients: Fluticasone propionate/Salmeterol xinafoate

Consumer Medicine Information (CMI)

This leaflet provides important information about using FLUTICASONE SALMETEROL CIPHALER 500/50. **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 FLUTICASONE SALMETEROL CIPHALER 500/50.**

Where to find information in this leaflet:

- [1. Why am I using FLUTICASONE SALMETEROL CIPHALER 500/50?](#)
- [2. What should I know before I use FLUTICASONE SALMETEROL CIPHALER 500/50?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FLUTICASONE SALMETEROL CIPHALER 500/50?](#)
- [5. What should I know while using FLUTICASONE SALMETEROL CIPHALER 500/50?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using FLUTICASONE SALMETEROL CIPHALER 500/50?

FLUTICASONE SALMETEROL CIPHALER 500/50 contains the active ingredients fluticasone propionate and salmeterol (as xinafoate).

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.

Corticosteroids have an anti-inflammatory action. They reduce the swelling and irritation in the walls of the small air passages in the lungs and so help you to breathe more easily. Corticosteroids are used to treat asthma and COPD.

Salmeterol (as xinafoate) is a bronchodilator. A bronchodilator keeps the breathing tubes in your lungs open and relieves the symptoms of asthma and other chest conditions. The effects of salmeterol (as xinafoate) last for up to twelve hours.

When taken together regularly fluticasone propionate and salmeterol help to control your breathing difficulties.

FLUTICASONE SALMETEROL CIPHALER 500/50 is used to help with asthma and chronic obstructive pulmonary disease (COPD) in people who need regular treatment.

Asthma is a condition affecting the lungs. Symptoms of asthma include shortness of breath, wheezing, chest

tightness and cough. Two main causes of asthma symptoms are bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

Chronic obstructive pulmonary disease (COPD) is a long-term condition affecting the lungs, resulting from chronic bronchitis or emphysema. Symptoms of COPD include shortness of breath, cough, chest discomfort and coughing up phlegm. The COPD symptoms are mainly due to bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

DO NOT use this medicine to treat a sudden attack of breathlessness as it will not help you. You will need a different type of medicine, e.g. VENTOLIN (salbutamol), which you must not confuse with FLUTICASONE SALMETEROL CIPHALER 500/50.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

FLUTICASONE SALMETEROL CIPHALER 500/50 is available as a dry powder device known as an "inhaler".

- FLUTICASONE SALMETEROL CIPHALER 500/50 (500 microgram fluticasone propionate and 50 microgram salmeterol)

2. What should I know before I use FLUTICASONE SALMETEROL CIPHALER 500/50?

Warnings

Do not use FLUTICASONE SALMETEROL CIPHALER 500/50 if:

- you are allergic to fluticasone propionate or salmeterol (as xinafoate), lactose monohydrate or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include wheezing or difficulty breathing, swelling of the face, eyelids, lips/mouth, tongue or throat, chest pain or tightness, hay fever or lumpy rash or fainting.
- always check the ingredients to make sure you can use this medicine.
- the expiry date (EXP) printed on the pack has passed or if the packaging is torn and shows signs of

tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

- have any allergies to any other medicines, foods, preservatives or dyes.
- have any other medical conditions, including thrush in your mouth, tuberculosis, diabetes, a thyroid condition, high blood pressure or a heart problem, low blood potassium levels.
- are taking other steroid medicines by mouth or inhalation.
- take any medicines for any other condition.

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 can discuss with you the risks and benefits involved.

FLUTICASONE SALMETEROL CIPHALER 500/50 contains lactose monohydrate

This medicine contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), talk to your doctor before taking this medicine.

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 FLUTICASONE SALMETEROL CIPHALER 500/50 and affect how it works.

These include:

- Beta-blockers used to treat high blood pressure (hypertension)
- Ketoconazole used to treat fungal infection
- Ritonavir used to treat HIV infection

These medicines may be affected by FLUTICASONE SALMETEROL CIPHALER 500/50 or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are

taking and if these affect FLUTICASONE SALMETEROL CIPHALER 500/50.

4. How do I use FLUTICASONE SALMETEROL CIPHALER 500/50?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

It is very important that you use the medicine regularly every day. Do not stop treatment even if you feel better unless told to do so by your doctor.

Do not change your dose unless told to by your doctor.

If you are breathless or wheezing more often than normal, tell your doctor.

Asthma

Adults and adolescents 12 years and older:

Your doctor will prescribe a different strength of fluticasone propionate/salmeterol for you, depending on the severity of your condition. Lower strength fluticasone/salmeterol inhalers (100/50 & 250/50) may be available from other brands.

The usual dose is one puff from your FLUTICASONE SALMETEROL CIPHALER 500/50 twice a day.

Children below 12 years of age:

FLUTICASONE SALMETEROL CIPHALER 500/50 is not recommended in children below 12 years of age.

COPD

Adults:

Your doctor will prescribe 1 or 2 different strengths of fluticasone propionate/salmeterol for you – either 250/50 or 500/50.

The usual dose is one puff from your FLUTICASONE SALMETEROL CIPHALER 500/50 twice a day.

Follow the instructions provided and use FLUTICASONE SALMETEROL CIPHALER 500/50 until your doctor tells you to stop.

When to take FLUTICASONE SALMETEROL CIPHALER 500/50

Your doctor has chosen this medicine to suit you and your condition. FLUTICASONE SALMETEROL CIPHALER 500/50 is used to help with asthma and COPD in people who need regular treatment.

It is very important that you use your FLUTICASONE SALMETEROL CIPHALER 500/50 every day, twice a day. This will help you to keep free of symptoms throughout the day and night.

Take your medicine at about the same time(s) each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

How to take FLUTICASONE SALMETEROL CIPHALER 500/50

The medicine in FLUTICASONE SALMETEROL CIPHALER 500/50 should be inhaled into your lungs.

FLUTICASONE SALMETEROL CIPHALER 500/50 must only be breathed in through the mouth.

Instructions for use

- Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using the FLUTICASONE SALMETEROL CIPHALER 500/50 properly or as prescribed may mean that it will not help your asthma as it should.
- The inhaler device holds blisters containing salmeterol and fluticasone as a powder.
- There is a counter on top of the inhaler which tells you how many doses are left. It counts down to 0. The numbers 5 to 0 will appear in red to warn you when there are only a few doses left. Once the counter shows 0, your inhaler is empty. See Figure A.



Figure A

Using your inhaler

1. To open your FLUTICASONE SALMETEROL CIPHALER 500/50, hold the outer case in one hand and put the thumb of your other hand on the thumbgrip. Push your thumb away from you as far as it will go. You will

hear a click. This will open a small hole in the mouthpiece. See Figure B



Figure B

2. Hold your inhaler with the mouthpiece towards you. You can hold it in either your right or left hand. Slide the lever away from you as far as it will go. You will hear a click. This places a dose of your medicine in the mouthpiece. See Figure C.



Figure C

Every time the lever is pulled back a blister is opened inside and the powder made ready for you to inhale. Do not play with the lever as this opens the blisters and wastes medicine.

3. Hold the inhaler away from your mouth, breathe out as far as is comfortable. Do not breathe into your inhaler. See Figure D.



Figure D

4. Put the mouthpiece to your lips; breathe in steadily and deeply through the inhaler, not through your nose. See Figure E.
 - Remove the inhaler from your mouth.

- Hold your breath for about 10 seconds or for as long as is comfortable.
- Breathe out slowly.



Figure E

5. Afterwards, rinse your mouth with water and spit it out, and/or brush your teeth. This may help to stop you getting thrush and becoming hoarse. See Figure F.



Figure F

6. To close the inhaler, slide the thumbgrip back towards you, as far as it will go. You will hear a click. The lever will return to its original position and is reset. See Figure G.

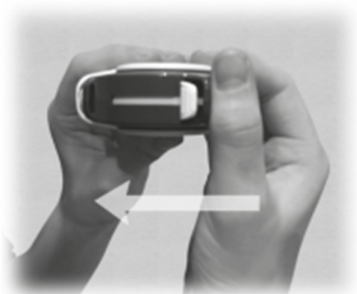


Figure G

Your inhaler is now ready for you to use again. As with all inhalers, caregivers should ensure that children prescribed FLUTICASONE SALMETEROL CIPHALER 500/50 use correct inhalation technique, as described above.

Cleaning your inhaler

Wipe the mouthpiece of the FLUTICASONE SALMETEROL CIPHALER 500/50 with a dry tissue to clean it.

If you have any difficulties or do not understand the instructions, ask your doctor or pharmacist.

Your FLUTICASONE SALMETEROL CIPHALER 500/50 inhaler is hygienically protected. It requires no maintenance and no refilling.

Use your medicine as your doctor has told you. If you are not sure ask your doctor or pharmacist.

After using FLUTICASONE SALMETEROL CIPHALER 500/50

Some people find that their mouth, throat or tongue becomes sore or that their voice becomes hoarse after inhaling this medicine. It may be helpful to rinse your mouth with water and spit it out after using your FLUTICASONE SALMETEROL CIPHALER 500/50. Tell your doctor but do not stop treatment unless told to do so.

If you forget to use FLUTICASONE SALMETEROL CIPHALER 500/50

FLUTICASONE SALMETEROL CIPHALER 500/50 should be used regularly at the same time each day. If you miss your dose at the usual time, **if it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.** Otherwise, use it as soon as you remember, then go back to using it as you would normally.

Do not use a double dose to make up for the dose that 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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much FLUTICASONE SALMETEROL CIPHALER 500/50

If you think that you have used too much FLUTICASONE SALMETEROL CIPHALER 500/50, 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.

Symptoms of an overdose may include:

- rapid heart beat
- increased rate of breathing
- significant muscle tremor
- headache

- increased blood pressure
- increased blood sugar (glucose) levels

If you are not sure what to do, contact your doctor or pharmacist.

5. What should I know while using FLUTICASONE SALMETEROL CIPHALER 500/50?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking FLUTICASONE SALMETEROL CIPHALER 500/50.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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 become pregnant while taking this medicine, or are trying to become pregnant, tell your doctor immediately. If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

- Keep all of your doctor's appointments so that your progress can be checked. Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.

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
- Experience a change in your vision
- Notice any symptoms listed in section 6

Things you should not do

- Do not take FLUTICASONE SALMETEROL CIPHALER 500/50 to treat any other complaints unless your doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you, or their symptoms seem similar to yours. Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Driving or using machines

This medicine is not expected to affect your ability to drive a car or operate machinery. It is prudent to be careful driving or operating machinery until you know how FLUTICASONE SALMETEROL CIPHALER 500/50 affects you.

Looking after your medicine

- Store below 25°C.

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 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.

If your breathing or wheezing gets worse straight after using your inhaler, stop using it immediately and tell your doctor as soon as possible.

Less serious side effects

Less serious side effects	What to do
Mouth/throat: <ul style="list-style-type: none"> • hoarseness • soreness of mouth, throat or tongue • soreness in the oesophagus 	Speak to your doctor if you have any of these less serious side effects and they worry you.
Cardiovascular: <ul style="list-style-type: none"> • increased blood pressure • increase in heart rate 	
Pain: <ul style="list-style-type: none"> • headache • muscle cramps • pains in joints 	
Skin: <ul style="list-style-type: none"> • skin rash • bruises 	

Anxiety and behavioural changes: <ul style="list-style-type: none"> • sweating, trembling, feeling nervous or anxious • sleep disturbances • unusual activity and irritability (mainly in children) Other: <ul style="list-style-type: none"> • slowing of growth in children and adolescents 	
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Serious side effects

Serious side effects	What to do
Allergic Reaction: <ul style="list-style-type: none"> • wheezing or difficulty breathing • swelling of the face, eyelids, lips/mouth, tongue or throat • chest pain or tightness • hay fever or lumpy rash ("hives") • fainting Respiratory: <ul style="list-style-type: none"> • pneumonia (lung infection) • shortness of breath Cardiovascular: <ul style="list-style-type: none"> • irregular heartbeat Ocular: <ul style="list-style-type: none"> • eye problems (e.g. cataract, glaucoma) Other: <ul style="list-style-type: none"> • rounded face 	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.

Some side effects, for example changes in blood sugar (glucose) level, blood pressure or loss of bone density can only be found when your doctor does tests from time to time to check your progress.

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.

Your doctor will be able to answer any questions you may have.

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 FLUTICASONE SALMETEROL CIPHALER 500/50 contains

Active ingredient (main ingredient)	fluticasone propionate salmeterol (as xinafoate)
Other ingredients (inactive ingredients)	lactose monohydrate

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

What FLUTICASONE SALMETEROL CIPHALER 500/50 looks like

FLUTICASONE SALMETEROL CIPHALER 500/50 is a plastic inhaler device containing a foil strip of 60 blisters, containing medicine in a powder form.

Each blister contains 500 micrograms of the active ingredient fluticasone propionate.

Each blister also contains 50 micrograms of the active ingredient salmeterol.

Each blister also contains lactose monohydrate as a carrier.

The blisters protect the powder for inhalation from the effects of the atmosphere.

The FLUTICASONE SALMETEROL CIPHALER 500/50 inhaler device has a numeric dose counter which tells you the number of doses remaining. It counts down from 60 to 0. The numbers appear in red when the last five doses have been reached.

Never use your FLUTICASONE SALMETEROL CIPHALER 500/50 inhaler if the dose counter reads 0. When the counter shows 0 your FLUTICASONE SALMETEROL

CIPHALER 500/50 inhaler is empty and should be disposed of.

Who distributes FLUTICASONE SALMETEROL CIPHALER 500/50

Cipla Australia Pty Ltd.,
Level 1, 132-136 Albert Road,
South Melbourne, VIC 3205.
drugsafety@cipla.com
Toll Free number: 1800 569 074.

FLUTICASONE SALMETEROL CIPHALER 500/50

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This leaflet was prepared in September 2022.