

FLUTICASONE SALMETEROL CIPHALER 250/50

250 microgram/50 microgram dose inhalation powder, pre-dispensed

Fluticasone propionate/Salmeterol xinafoate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using FLUTICASONE SALMETEROL CIPHALER 250/50.

This leaflet answers some common questions about FLUTICASONE SALMETEROL CIPHALER 250/50. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking FLUTICASONE SALMETEROL CIPHALER 250/50 against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What FLUTICASONE SALMETEROL CIPHALER 250/50 is used for

FLUTICASONE SALMETEROL CIPHALER 250/50 (250 microgram fluticasone propionate and 50 microgram salmeterol) is available as a dry powder device called an inhaler.

FLUTICASONE SALMETEROL CIPHALER 250/50 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).

How FLUTICASONE SALMETEROL CIPHALER 250/50 works

FLUTICASONE SALMETEROL CIPHALER 250/50 contains two medicines, 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.

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 250/50.

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.

Before you use FLUTICASONE SALMETEROL CIPHALER 250/50

When you must not take it

Do not take FLUTICASONE SALMETEROL CIPHALER 250/50 if you have an allergy to:

- any medicine containing fluticasone propionate
- any medicine containing salmeterol (as xinafoate)
- lactose monohydrate
- any of the ingredients listed at the end of this leaflet.

Some of the 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 ("hives")
- fainting

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If you use it after the expiry date has passed, it may not work as well.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- thrush in your mouth
- tuberculosis
- diabetes
- a thyroid condition
- high blood pressure or a heart problem

- low blood potassium levels

Tell your doctor if you are taking other steroid medicines by mouth or inhalation.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking FLUTICASONE SALMETEROL CIPHALER 250/50.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and FLUTICASONE SALMETEROL CIPHALER 250/50 may interfere with each other. 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 250/50 or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

FLUTICASONE SALMETEROL CIPHALER 250/50 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.

How to take FLUTICASONE SALMETEROL CIPHALER 250/50

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 FLUTICASONE SALMETEROL CIPHALER 250/50 for you, depending on the severity of your condition:

- FLUTICASONE SALMETEROL CIPHALER 250/50 (250 micrograms of fluticasone propionate and 50 micrograms of salmeterol)

The usual dose is one puff from your FLUTICASONE SALMETEROL CIPHALER 250/50 inhaler twice a day.

Children 4 years and older:

FLUTICASONE SALMETEROL CIPHALER 250/50 is not recommended for use in children below 12 years of age.

COPD

Adults:

Your doctor may prescribe the following strength of FLUTICASONE SALMETEROL CIPHALER 250/50 for you:

- FLUTICASONE SALMETEROL CIPHALER 250/50 (250 micrograms of fluticasone propionate and 50 micrograms of salmeterol)

The usual dose is one puff from your FLUTICASONE SALMETEROL CIPHALER 250/50 inhaler twice a day.

This brand of fluticasone/salmeterol is only available in one strength (fluticasone propionate and salmeterol 250 microgram/50 microgram). When it is appropriate to titrate to a dose of inhaled corticosteroid other than 250 micrograms, a change to an alternative fixed-dose combination of fluticasone propionate and salmeterol containing a different dose of the inhaled corticosteroid is required.

How to take it

The medicine in FLUTICASONE SALMETEROL CIPHALER 250/50 should be inhaled into your lungs.

FLUTICASONE SALMETEROL CIPHALER 250/50 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 250/50 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 250/50, 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.

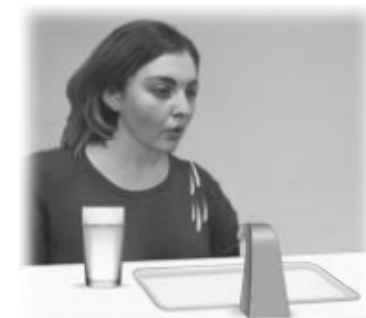


Figure F

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 250/50 use correct inhalation technique, as described above.

Cleaning your inhaler

Wipe the mouthpiece of the FLUTICASONE SALMETEROL CIPHALER 250/50 with a dry tissue to clean it.

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

FLUTICASONE SALMETEROL CIPHALER 250/50

Your FLUTICASONE SALMETEROL CIPHALER 250/50 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.

When to take it

Your doctor has chosen this medicine to suit you and your condition. FLUTICASONE SALMETEROL CIPHALER 250/50 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 250/50 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 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.

How long to take it

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.

If you forget to take it

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much FLUTICASONE SALMETEROL CIPHALER 250/50.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

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.

While you are using FLUTICASONE SALMETEROL CIPHALER 250/50

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking FLUTICASONE SALMETEROL CIPHALER 250/50.

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.

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.

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.

Things you must not do

Do not take FLUTICASONE SALMETEROL CIPHALER 250/50 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.

Things to be careful of

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 250/50 affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FLUTICASONE

SALMETEROL CIPHALER 250/50, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

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

This medicine helps most people with asthma and COPD. Most people using this medicine find that it causes no problem, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Common Side Effects

- soreness in the mouth, throat, or tongue
- hoarseness
- headache
- muscle cramps
- pains in joints
- increase in heart rate

Pneumonia (lung infection) has been reported commonly in patients with COPD.

Uncommon Side Effects

- skin rash
- shortness of breath
- sweating, trembling, feeling nervous or anxious
- bruising
- Eye problems (e.g. cataract, glaucoma)
- sleep disturbances

Rare Side Effects

- swelling of the face, lips, mouth, tongue or throat
- irregular heartbeat
- behavioural changes, including unusual activity and irritability (mainly in children).
- Rounded face
- Slowing of growth in children and adolescents
- Soreness in the oesophagus

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital, as you may be having an allergic reaction:

- 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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.

If you have any side effects, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly at <http://www.tga.gov.au/reporting-problems>. By reporting side effects you can help provide more information on the safety of this medicine.

After using FLUTICASONE SALMETEROL CIPHALER 250/50

Rinse mouth after use

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 250/50. Tell your doctor but do not stop treatment unless told to do so.

Storage

Store below 25°C.

Do not store FLUTICASONE SALMETEROL CIPHALER 250/50 or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

FLUTICASONE SALMETEROL CIPHALER 250/50 is a white to off white powder filled in a foil blister strip of 60 blisters in a plastic inhaler.

Each blister contains 250 micrograms of the active ingredient fluticasone propionate.

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

The strength of FLUTICASONE SALMETEROL CIPHALER 250/50 is represented by a shade of colour on the carton and FLUTICASONE SALMETEROL CIPHALER 250/50 label.

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 250/50 inhaler device has a 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 250/50 inhaler if the dose counter reads 0. When the counter shows 0 your FLUTICASONE SALMETEROL CIPHALER 250/50 inhaler is empty and should be disposed of.

Ingredients

FLUTICASONE SALMETEROL CIPHALER 250/50 contains the active ingredients:

- fluticasone propionate
- salmeterol (as xinafoate)

Your FLUTICASONE SALMETEROL CIPHALER 250/50 also contains lactose monohydrate

Supplier

FLUTICASONE SALMETEROL CIPHALER 250/50 is supplied in Australia by:

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 250/50 – AUST R 331561

Date of preparation

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