

SALPLUSF® INHALER 125/25; SALPLUSF® INHALER 250/25

fluticasone propionate/salmeterol (as xinafoate)

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using SalplusF Inhaler.

This leaflet answers some common questions about SalplusF Inhaler. 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 SalplusF Inhaler 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 SalplusF Inhaler is used for

SalplusF Inhaler is available as a Metered Dose Inhaler (MDI).

- SalplusF Inhaler 125/25 (125 microgram fluticasone propionate and 25 microgram salmeterol), or
- SalplusF Inhaler 250/25 (250 microgram fluticasone propionate and 25 microgram salmeterol).

SalplusF Inhaler 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).

SalplusF Inhaler 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 SalplusF Inhaler.

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 SalplusF Inhaler

When you must not take it

Do not take SalplusF Inhaler if you have an allergy to:

- any medicine containing fluticasone propionate
- any medicine containing salmeterol (as xinafoate)
- 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 SalplusF Inhaler.

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 SalplusF Inhaler 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 SalplusF Inhaler 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.

How to take SalplusF Inhaler

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.

SalplusF Inhaler is not for use in patients aged under 12 years. A lower strength fluticasone and salmeterol (50/25 microgram) inhalation can be available from other brand/s.

ASTHMA

Adults and adolescents 12 years and older:

Your doctor will prescribe 1 of 2 different strengths of SalplusF Inhaler for you, depending on the severity of your condition:

- SalplusF Inhaler 125/25 (125 microgram fluticasone propionate and 25 microgram salmeterol), or
- SalplusF Inhaler 250/25 (250 microgram fluticasone propionate and 25 microgram salmeterol).

The usual dose is two puffs from your inhaler twice a day.

SalplusF Inhaler is only available in two strengths (fluticasone propionate and salmeterol 125/25 microgram and 250/25 microgram). It is not available in a lower strength product containing salmeterol 25 microgram and fluticasone propionate 50 microgram. Therefore, when it is appropriate to titrate down to a dose of inhaled corticosteroid below 125 micrograms, a change to an alternative fixed-dose combination of salmeterol and fluticasone propionate containing a lower dose of the inhaled corticosteroid is required.

COPD

Adults:

Your doctor will prescribe 1 of 2 different strengths of SalplusF Inhaler for you:

- SalplusF Inhaler 125/25 (125 microgram fluticasone propionate and 25 microgram salmeterol), or
- SalplusF Inhaler 250/25 (250 microgram fluticasone propionate and 25 microgram salmeterol).

The usual dose is two puffs from your inhaler twice a day.

How to take it

The medicine in SalplusF Inhaler should be inhaled into your lungs.

SalplusF Inhaler must only be breathed in through the mouth.

The full instructions for using SalplusF Inhaler is given on a leaflet inside the pack.

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

If you find it difficult to use your SalplusF Inhaler, talk to your doctor or pharmacist. It may be better for you to use something called a spacer device. Your doctor or pharmacist will explain 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 your SalplusF Inhaler is new and you have not used it before, shake it well, point the mouthpiece away from you and press the canister to release four puffs into the air. The dose indicator will show the number "120" indication the number of puffs in the inhaler.

If your SalplusF Inhaler has not been used for one week or more, you should release two puffs into the air before use.

As you use the inhaler the dose indicator will typically rotate during every five to seven puffs towards next decreasing number. The dose indicator will show the approximate no of puffs remaining in the inhaler.

In some cases dropping the inhaler may cause the indicator to count down.

Cleaning: Your Inhaler should be cleaned at least once a week as follows:

1. Remove the mouthpiece cover.
2. Do not remove the canister from the plastic casing.
3. Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth or tissue.
4. Replace the mouthpiece cover.

DO NOT PUT THE METAL CANISTER INTO WATER.

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. SalplusF Inhaler is used to help with asthma and COPD in people who need regular treatment.

It is very important that you use your SalplusF Inhaler 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 SalplusF Inhaler.

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 SalplusF Inhaler

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking SalplusF Inhaler.

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.

Things you must not do

Do not take SalplusF Inhaler 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

Be careful driving or operating machinery until you know how SalplusF Inhaler affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SalplusF Inhaler, 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 SalplusF 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.

After using SalplusF Inhaler

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 SalplusF Inhaler. Tell your doctor but do not stop treatment unless told to do so.

Storage

Keep your SalplusF Inhaler in a dry place where the temperature stays below 25°C, away from direct heat or sunlight.

Do not store inhaler in a cold place as it may not work as well.

Do not store SalplusF Inhaler 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.

If your SalplusF Inhaler becomes very cold, it may not work properly. Keep your Inhaler away from frost.

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

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

SalplusF Inhaler is available with a dose indicator. The MDI comprises a suspension of fluticasone propionate and salmeterol in a CFC-free propellant.

SalplusF 125/25 are a rigid, aluminium, container fitted with a metered dose valve, containing a white homogeneous suspension, fitted to a plastic actuator with a white coloured body and pink coloured cap, with a dose indicator.

SalplusF 250/25 are a rigid, aluminium, container fitted with a metered dose valve, containing a white homogeneous suspension, fitted to a plastic actuator with a white coloured body and rubin red coloured cap, with a dose indicator.

Each canister contains 120 doses of the medicine.

Each dose contains 125 or 250 micrograms of the active ingredient fluticasone propionate.

Each dose also contains 25 micrograms of active ingredient salmeterol. The amount depends on which strength of SalplusF Inhaler you have been given.

The canister has a indicator attached to show how many puffs of medicine you have left. The number of puffs left will show through a window in the back of the plastic casing. As you use the inhaler the dose indicator will typically rotate during every five to seven puffs towards next decreasing number. The dose indicator will show the approximate no of puffs remaining in the inhaler.

You should consider getting a replacement when the indicator shows the number 020.

Do not use your SalplusF Inhaler if the indicator shows 000. When the indicator shows 000 you must dispose of your SalplusF Inhaler.

Never try to alter the numbers on the indicator or detach the indicator from the metal canister. The indicator cannot be reset and is permanently attached to the canister.

Ingredients

SalplusF Inhaler contains the active ingredients:

- fluticasone propionate
- salmeterol (as xinafoate)

Your SalplusF Inhaler also contains HFA-134a, a CFC-Free propellant.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park NSW 2113
Australia
Tel: 1800 634 500

This leaflet was revised in June 2017.

Australian Register numbers:

125 microgram/25 microgram inhalation pressurised aerosol can metered dose: AUST R 267104

250 microgram/25 microgram inhalation pressurised aerosol can metered dose: AUST R 267105