Package leaflet: Information for the user

Salmeterol/Fluticasonpropionaat Sandoz 25/125 microgram, aerosol, suspensie
Salmeterol/Fluticasonpropionaat Sandoz 25/250 microgram, aerosol, suspensie

salmeterol /fluticasone propionate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Salmeterol/Fluticasonpropionaat Sandoz is and what it is used for

Salmeterol/Fluticasonpropionaat Sandoz contains two medicines, salmeterol and fluticasone propionate:
- Salmeterol is a long-acting bronchodilator. Bronchodilators help the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects last for at least 12 hours.
- Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

Salmeterol/Fluticasonpropionaat Sandoz is not recommended for use by children.

The doctor has prescribed this medicine to help prevent breathing problems such as asthma.
You must use Salmeterol/Fluticasonpropionaat Sandoz every day as directed by your doctor. This will make sure that it works properly in controlling your asthma.

Salmeterol/Fluticasonpropionaat Sandoz helps to stop breathlessness and wheeziness coming on. However Salmeterol/Fluticasonpropionaat Sandoz should not be used to relieve a sudden attack of breathlessness or wheezing. If this happens you need to use a fast-acting 'reliever' ('rescue') inhaler, such as salbutamol. You should always have your fast-acting 'rescue' inhaler with you.

2. What you need to know before you use Salmeterol/Fluticasonpropionaat Sandoz

Do not take Salmeterol/Fluticasonpropionaat Sandoz:
If you are allergic to salmeterol, fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before using Salmeterol/Fluticasonpropionaat Sandoz if you have:
- Heart disease, including an irregular or fast heart beat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (Salmeterol/Fluticasonpropionaat Sandoz may increase your blood sugar)
- Low potassium in your blood
- Tuberculosis (TB) now, or in the past, or other lung infections.

Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Salmeterol/Fluticasonpropionaat Sandoz
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines for asthma or any medicines obtained without a prescription. This is because Salmeterol/Fluticasonpropionaat Sandoz may not be suitable to be taken with some other medicines.

Tell your doctor if you are taking the following medicines, before starting to use Salmeterol/Fluticasonpropionaat Sandoz:
- β blockers (such as atenolol, propranolol and sotalol). β blockers are mostly used for high blood pressure or other heart conditions.
- Medicines to treat infections including some medicines for HIV (such as ritonavir, cobicistat, ketoconazole, itraconazole and erythromycin). Some of these medicines may increase the amount of fluticasone propionate or salmeterol in your body. This can increase your risk of experiencing side effects with Salmeterol/Fluticasonpropionaat Sandoz, including irregular heartbeats, or may make side effects worse. Your doctor may wish to monitor you carefully if you are taking these medicines.
- Corticosteroids (by mouth or by injection). If you have had these medicines recently, this might increase the risk of this medicine affecting your adrenal gland.
- Diuretics, also known as ‘water tablets’ used to treat high blood pressure.
- Other bronchodilators (such as salbutamol).
- Xanthine medicines. These are often used to treat asthma.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Salmeterol/Fluticasonpropionaat Sandoz is not likely to affect your ability to drive or use machines.

3. How to use Salmeterol/Fluticasonpropionaat Sandoz

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Use your Salmeterol/Fluticasonpropionaat Sandoz every day, until your doctor advises you to stop. Do not take more than the recommended dose. Check with your doctor or pharmacist if you are not sure.
- Do not stop taking Salmeterol/Fluticasonpropionaat Sandoz or reduce the dose of Salmeterol/Fluticasonpropionaat Sandoz without talking to your doctor first
- Salmeterol/Fluticasonpropionaat Sandoz should be inhaled through the mouth into the lungs.

The recommended dose is:
Adults

- Salmeterol/Fluticasonpropionaat Sandoz 25/125 - 2 puffs twice a day
- Salmeterol/Fluticasonpropionaat Sandoz 25/250 - 2 puffs twice a day

Your symptoms may become well controlled using Salmeterol/Fluticasonpropionaat Sandoz twice a day. If so, your doctor may decide to reduce your dose to once a day. The dose may change to:

- once at night - if you have **night-time** symptoms
- once in the morning - if you have **daytime** symptoms.

It is very important to follow your doctor's instructions on how many puffs to take and how often to take your medicine.

If you are using Salmeterol/Fluticasonpropionaat Sandoz for asthma, your doctor will want to regularly check your symptoms.

If your asthma or breathing gets worse tell your doctor straight away. You may find that you feel more wheezy, your chest feels tight more often or you may need to use more of your fast-acting 'reliever' medicine. If any of these happen, you should continue to take Salmeterol/Fluticasonpropionaat Sandoz but do not increase the number of puffs you take. Your chest condition may be getting worse and you could become seriously ill. See your doctor as you may need additional treatment.

Use in children
Salmeterol/Fluticasonpropionaat Sandoz is not recommended for use by children.

Instructions for use

- Your doctor or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using the Salmeterol/Fluticasonpropionaat Sandoz inhaler properly or as prescribed may mean that it will not help your asthma as it should.
- The medicine is contained in a pressurised canister in a plastic casing with a mouthpiece.
- There is an indicator in front of the inhaler which tells you how many doses are left. 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
- Take care not to drop the inhaler as this may cause the indicator to count down.

Testing your inhaler

1. When using your inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.

2. To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release 4 puffs into the air, shaking the inhaler before releasing each puff. The indicator displays the number 120, the number of puffs contained in the inhaler. If you have not used your inhaler for a week or more, release two puffs of medicine into the air.

Using your inhaler
It is important to start to breathe as slowly as possible just before using your inhaler.

1. Stand or sit upright when using your inhaler.

2. Remove the mouthpiece cover (as described in step 1 of Testing your inhaler). Check inside and outside to make sure that the mouthpiece is clean and free of loose objects (figure A).

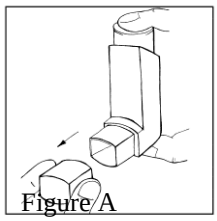
Figure A

3. Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed (figure B).

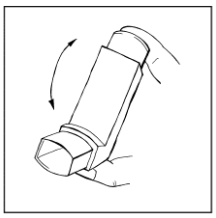

Figure B

4. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable (figure C).

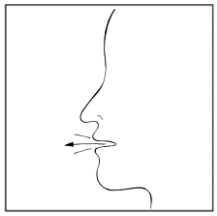

Figure C

5. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite (figure D).

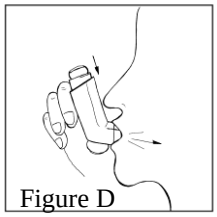

Figure D

6. Breathe in through your mouth slowly and deeply. Just after starting to breathe in, press firmly down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply (figure D).

7. Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable (figure E).

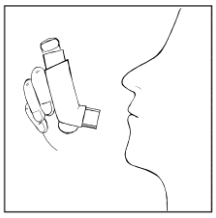

Figure E

8. Between taking each puff of medicine, wait about half a minute and then repeat steps 3 to 7.

9. 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.

10. After use always replace the mouthpiece cover straight away to keep out dust. When the mouthpiece cover is fitted correctly it will ‘click’ into position. If it does not ‘click’ into place, turn the mouthpiece cover the other way round and try again. Do not use too much force.

Do not rush steps 4, 5, 6 and 7. It is important that you breathe in as slowly as possible just before using your inhaler. You should use your inhaler whilst standing in front of a mirror for the first few times. If you see "mist" coming from the top of your inhaler or the sides of your mouth, you should start again from step 3.

If you find it difficult to use the inhaler, either your doctor or other healthcare provider may recommend using a spacer device such as the Volumatic® or AeroChamber Plus® (depending on National Guidance) with your inhaler. Your doctor, pharmacist or other healthcare provider should show you how to use the spacer device with your inhaler and how to care for your spacer device and will answer any questions you may have. It is important that if you are using a spacer device with your inhaler that you do not stop using it without talking to your doctor first. It is also important that you do not change the type of spacer device that you use without talking to your doctor. If you stop using a spacer device or change the type of spacer device that you use your doctor may need to change the dose of medicine required to control your asthma.
Always talk to your doctor before making any changes to your asthma treatment.

People with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece.

You should get a replacement when the indicator shows the number ‘40’ and the color on the dose indicator will change from green to red. Stop using the Inhaler when the indicator shows ‘0’ as any puffs left in the device may not be enough to give you a full dose. Never try to alter the numbers on the indicator or detach the indicator from the actuator. The indicator cannot be reset and is permanently attached to the actuator.

Cleaning your inhaler
To stop your inhaler blocking, it is important to clean it at least once a week.

To clean your inhaler:

- Remove the mouthpiece cover.
- Do not remove the metal canister from the plastic casing at any time.
- Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth or tissue.
- Replace the mouthpiece cover. It will 'click' into place when fitted correctly. If it does not 'click' into place, turn the mouthpiece cover the other way round and try again. Do not use too much force.

Do not put the metal canister in water.

If you use more Salmeterol/Fluticasonpropionaat Sandoz than you should
It is important to use the inhaler as instructed. If you accidentally take a larger dose than recommended, talk to your doctor or pharmacist. You may notice your heart beating faster than usual and that you feel shaky. You may also have dizziness, a headache, muscle weakness and aching joints.

If you have used larger doses for a long period of time, you should talk to your doctor or pharmacist for advice. This is because larger doses of Salmeterol/Fluticasonpropionaat Sandoz may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use Salmeterol/Fluticasonpropionaat Sandoz
Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you stop using Salmeterol/Fluticasonpropionaat Sandoz
It is very important that you take your Salmeterol/Fluticasonpropionaat Sandoz every day as directed. **Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of Salmeterol/Fluticasonpropionaat Sandoz.** This could make your breathing worse.

In addition, if you suddenly stop taking Salmeterol/Fluticasonpropionaat Sandoz or reduce your dose of Salmeterol/Fluticasonpropionaat Sandoz this may (very rarely) cause you to have problems with your adrenal gland (adrenal insufficiency) which sometimes causes side effects.
These side effects may include any of the following:

- Stomach pain
- Tiredness and loss of appetite, feeling sick
- Sickness and diarrhoea
- Weight loss
- Headache or drowsiness
- Low levels of sugar in your blood

- Low blood pressure and seizures (fits)

When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, adrenal insufficiency can get worse and you may have any of the side effects listed above. If you get any side effects, talk to your doctor or pharmacist. To prevent these symptoms occurring, your doctor may prescribe extra corticosteroids in tablet form (such as prednisolone).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. To reduce the chance of side effects, your doctor will prescribe the lowest dose of Salmeterol/Fluticasonpropionaat Sandoz to control your asthma.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Salmeterol/Fluticasonpropionaat Sandoz. You may be very wheezy and cough or be short of breath. You may also notice itching, a rash (hives) and swelling (usually of the face, lips, tongue or throat), or you may suddenly feel that your heart is beating very fast or you feel faint and light headed (which may lead to collapse or loss of consciousness). **If you get any of these effects or if they happen suddenly after using Salmeterol/Fluticasonpropionaat Sandoz, stop using Salmeterol/Fluticasonpropionaat Sandoz and tell your doctor straight away.** Allergic reactions to Salmeterol/Fluticasonpropionaat Sandoz are uncommon (they may affect up to 1 in 100 people).

Other side effects are listed below:

Very common (may affect more than 1 in 10 people)

- Headache - this usually gets better as treatment continues.
- Increased number of colds have been reported in patients with COPD.

Common (may affect up to 1 in 10 people)

- Thrush (sore, creamy-yellow, raised patches) in the mouth and throat. Also sore tongue and hoarse voice and throat irritation. Rinsing your mouth out with water and spitting it out immediately and/or brushing your teeth after taking each dose of your medicine may help. Your doctor may prescribe an anti-fungal medication to treat the thrush.
- Aching, swollen joints and muscle pain.
- Muscle cramps.

The following side effects have also been reported in patients with Chronic Obstructive Pulmonary Disease (COPD):

- Pneumonia and bronchitis (lung infection). Tell your doctor if you notice any of the following symptoms: increase in sputum production, change in sputum colour, fever, chills, increased cough, increased breathing problems.
- Bruising and fractures.
- Inflammation of sinuses (a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache)
- A reduction in the amount of potassium in the blood (you may get an uneven heartbeat, muscle weakness, cramp).

Uncommon (may affect up to 1 in 100 people)

- Increases in the amount of sugar (glucose) in your blood (hyperglycaemia). If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetic treatment may be required.
- Cataract (cloudy lens in the eye).
- Very fast heartbeat (tachycardia).
- Feeling shaky (tremor) and fast or uneven heart beat (palpitations) - these are usually harmless and get less as treatment continues.
- Chest pain.
- Feeling worried (this effect mainly occurs in children).
- Disturbed sleep.
- Allergic skin rash.

Rare (may affect up to 1 in 1,000 people)

- **Breathing difficulties or wheezing that get worse straight after taking Salmeterol/Fluticasonpropionaat Sandoz.** If this happens **stop using your Salmeterol/Fluticasonpropionaat Sandoz inhaler**. Use your fast-acting ‘reliever’ inhaler to help your breathing and **tell your doctor straight away**.
- Salmeterol/Fluticasonpropionaat Sandoz may affect the normal production of steroid hormones in the body, particularly if you have taken high doses for long periods of time. The effects include:
    - Slowing of growth in children and adolescents
    - Thinning of the bones

- Glaucoma
- Weight gain
- Rounded (moon shaped) face (Cushing's Syndrome)

Your doctor will check you regularly for any of these side effects and make sure you are taking the lowest dose of Salmeterol/Fluticasonpropionaat Sandoz to control your asthma.

- Behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).
- Uneven heart beat or heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking Salmeterol/Fluticasonpropionaat Sandoz unless the doctor tells you to stop.
- A fungal infection in the oesophagus (gullet), which might cause difficulties in swallowing.

Frequency not known (frequency cannot be estimated from the available data), but may also occur:

- Depression or aggression. These effects are more likely to occur in children
- Blurred vision.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via {the national reporting system listed in Appendix V}*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Salmeterol/Fluticasonpropionaat Sandoz

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening pouch: use within 3 months

Store below 25°C.

Keep the container in the outer carton in order to protect from light.
The container contains a pressurised liquid.
Do not expose to temperatures higher than 50°C.
Do not pierce the canister.

The container should not be punctured, broken or burnt even when apparently empty.

Do not refrigerate or freeze.
As with most inhaled medicinal products in pressurised containers, the therapeutic effect of this medicinal product may decrease when the container is cold.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Salmeterol/Fluticasonpropionaat Sandoz contains
<{Salmeterol/Fluticasonpropionaat Sandoz 25 micrograms/125 micrograms per dose - pressurised inhalation, suspension}>
The active substances are salmeterol (as salmeterol xinafoate) and fluticasone propionate. Each metered dose provides 25 micrograms of salmeterol (as salmeterol xinafoate) and 125 micrograms of fluticasone propionate.
The other ingredient is norflurane (HFA 134a) as propellant.

<{Salmeterol/Fluticasonpropionaat Sandoz 25 micrograms/250 micrograms per dose - pressurised inhalation, suspension}>
The active substances are salmeterol (as salmeterol xinafoate) and fluticasone.
Each metered dose provides 25 micrograms of salmeterol (as salmeterol xinafoate) and 250 micrograms of fluticasone propionate.
The other ingredient is norflurane (HFA 134a) as propellant.

What Salmeterol/Fluticasonpropionaat Sandoz looks like and contents of the pack
The inhaler consists of an aluminium container with a suitable metering valve and a polypropylene actuator with dose indicator and fitted with polypropylene (PP) dust cap in a sealed pouch with a silica gel bag packed into carton box.
The container contains a white homogeneous suspension.
Each container is filled to deliver 120 actuations.

[NL/H/3707]
Pack size:
1; 2; 2 (bundled package 2x1); 3; 3 (bundled package 3x1); 4; 5; 6; 10; 10 (bundled package 10x1) x 120 actuations inhaler(s)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland
Correspondentie: Postbus 10332, 1301 AH Almere

Fabrikant

Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

In het register ingeschreven onder:
Salmeterol/Fluticasonpropionaat Sandoz 25/125 microgram, aerosol, suspensie: RVG 118829
Salmeterol/Fluticasonpropionaat Sandoz 25/250 microgram, aerosol, suspensie: RVG 118833

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Salmeterol/Fluticasonpropionaat Sandoz 25/125 microgram, aerosol, suspensie Salmeterol/Fluticasonpropionaat Sandoz 25/250 microgram, aerosol, suspensie
Oostenrijk	Airflusal® Dosieraerosol 25 Mikrogramm/125 Mikrogramm pro Dosis - Druckgasinhalation, Suspension Airflusal® Dosieraerosol 25 Mikrogramm/250 Mikrogramm pro Dosis - Druckgasinhalation, Suspension
België	Airflusal sprayhaler 25 microgram/125 microgram per afgemeten dosis aërosol,suspensie Airflusal sprayhaler 25 microgram/250 microgram per afgemeten dosis aërosol, ` suspensie
Bulgarije:	AirFluSal Sprayhaler 25 micrograms/125 micrograms pressurised inhalation, suspension AirFluSal Sprayhaler 25 micrograms /250 micrograms pressurised inhalation, suspension
Tsjechië	Airflusan Sprayhaler
Duitsland	Airflusal Dosieraerosol
Denemarken	AirFluSal Sprayhaler
Finland	AirFluSal Sprayhaler
Kroatië	Airflusal 25 /125 mikrograma po potisku, stlačeni inhalat, suspenzija Airflusal 25 /250 mikrograma po potisku, stlačeni inhalat, suspenzija
Hongarije	AirFluSol Sprayhaler 25 mikrogramm/125 mikrogramm/adag túlnyomásos inhalációs szuszpenzió AirFluSol Sprayhaler 25 mikrogramm/250 mikrogramm/adag túlnyomásos inhalációs szuszpenzió
Ierland	AirFluSal MDI 25 microgram/125 microgram/dose pressurised inhalation, suspension AirFluSal MDI 25 microgram/250 microgram/dose pressurised inhalation suspension
Italie	Salmeterolo e Fluticasone Sandoz GmbH
Litouwen	AirFlusal 25/125 mikrogramai/dozėje suslėgtoji įkvepiamoji suspensija AirFlusal 25/250 mikrogramai/dozėje suslėgtoji įkvepiamoji suspensija
Letland	AirFluSal 25/125 mikrogrami/deva aerosols inhalācijām, zem spiediena, suspensija AirFluSal 25/250 mikrogrami/deva aerosols inhalācijām, zem spiediena, suspensija
Noorwegen	Airflusal Sprayhaler
Polen	AirFluSal
Roemenië	AirFluSal 25 microgram/125 microgram suspensie de inhalat presurizată AirFluSal 25 microgram/250 microgram suspensie de inhalat presurizată

Slovenië	Airflusan 25 mikrogramov/125 mikrogramov/vpih inhalacijska suspenzija pod tlakom Airflusan 25 mikrogramov/250mikrogramov/vpih inhalacijska suspenzija pod tlakom
Slowakije	Airflusal 25 mikrogramov/125 mikrogramov Airflusal 25 mikrogramov/250 mikrogramov

Deze bijsluiter is voor het laatst goedgekeurd juli 2023