

Package leaflet: Information for the user

AirFluSal® Aerosol 25/125 microgram, aerosol, suspension

AirFluSal® Aerosol 25/250 microgram, aerosol, suspension

salmeterol (as salmeterol xinafoate)/fluticasone propionate

Read the entire 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.

Do you have any further questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet:

1. What is AirFluSal Aerosol and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the package and other information

## 1. What is AirFluSal Aerosol and what is it used for?

AirFluSal Aerosol contains two medicines: salmeterol and fluticasone propionate:

Salmeterol is a long-acting bronchodilator. Bronchodilators help keep the airways in the lungs open. This makes it easier to breathe air in and out. The effect lasts for at least 12 hours.

Fluticasone propionate is a corticosteroid that reduces swelling and irritation in the lungs.

This medicine is not recommended for use in children.

Your doctor has prescribed this medicine to help prevent breathing problems such as asthma. You must use this medicine daily as directed by your doctor. This ensures that it works well in controlling your asthma.

This medicine helps to stop the occurrence of tightness and shortness of breath. However, it should not be used to relieve a sudden attack of tightness or shortness of breath. If this happens, you should use a fast-acting relief "rescue" inhaler such as salbutamol. You should always have your fast-acting "rescue" inhaler with you.

## 2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine if you have any of the following:

- a heart disease, including an irregular or fast heartbeat;
- an overactive thyroid;
- high blood pressure;
- diabetes mellitus (this medicine can increase your blood sugar);
- a low potassium level in your blood;
- tuberculosis (TB), if you have it or have had it in the past, or other lung infections.

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

Are you using any other medicines?

Are you using any other medicines besides AirFluSal Aerosol, have you recently done so, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines for asthma and medicines that you can obtain without a prescription. This is because this medicine may not be suitable to use at the same time as some other medicines.

Tell your doctor if you are using the following medicines before you start using AirFluSal Aerosol:

Beta-blockers (such as atenolol, propranolol, and sotalol). Beta-blockers are usually used to treat high blood pressure or other heart conditions.

Medicines for the treatment of infections, including some medicines for HIV (such as ritonavir, cobicistat, ketoconazole, itraconazole, and erythromycin). Some of these medicines can increase the amount of fluticasone propionate or salmeterol in your body. This can increase the risk of side effects with AirFluSal Aerosol, including an irregular heartbeat, or it can worsen side effects. Your doctor may want to monitor you carefully if you are using these medicines.

Corticosteroids (taken orally or administered by injection). If you have recently had these medicines, this medicine may increase the risk of adrenal impairment.

Diuretics, also known as water pills, which are used to treat high blood pressure.

Other bronchodilators (such as salbutamol).

Xanthine medicines. These are often used to treat asthma.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive and use machines.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Use this medicine every day until your doctor advises you to stop. Do not use more than the recommended dosage. If in doubt, contact your doctor or pharmacist.

You should not stop or reduce the use of this medicine without first discussing it with your doctor.

This medicine must be inhaled through the mouth into the lungs.

The recommended dosage is: Adults

AirFluSal Aerosol 25/125: two puffs twice a day

AirFluSal Aerosol 25/250: two puffs twice a day

If you use this medicine twice a day, your symptoms can be well controlled. If that is the case, your doctor may decide to reduce your dosage to once a day. The dosage can be changed to:  
once at night – if symptoms occur during the night  
once in the morning – if symptoms occur during the day

It is very important that you follow your doctor's instructions on the number of puffs you should administer and how often you should use your medicine.

If you are using this medicine for asthma, your doctor will want to regularly check your symptoms.

If your asthma or breathing gets worse, tell your doctor immediately. You may notice that you are wheezing more, that you have a tight feeling in your chest more often, or that you need to use your fast-acting rescue medication more. If any of the above symptoms occur, you should continue to use this medicine but do not increase the number of puffs. Your condition may worsen and you could become seriously ill. See your doctor as you may need additional treatment.

Use in children

This medicine is not recommended for use by children.

Instructions for use

Your doctor or pharmacist should give you instructions on the correct use of your inhaler. They should regularly check how you use the inhaler. If you do not use the inhaler of this medicine correctly or as prescribed, it may mean that it does not help your asthma as it should.

The medicine is contained in a pressurized metal canister, placed in a plastic holder with a mouthpiece.

The inhaler has an indicator on the front that shows you how many doses are left. When you use the inhaler, the dose indicator typically counts down a number after every 5 to 7 puffs. The dose indicator shows approximately how many puffs are left in the inhaler.

Do not drop the inhaler, as this may cause the indicator to count down.

Testing your inhaler

1. If you are using your inhaler for the first time, test if it works. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pulling the cover off.
2. To ensure it works, shake the inhaler well, point the mouthpiece away from you, and press the canister; spray 4 puffs into the air while shaking the inhaler each time before spraying a puff into the air. The dose indicator shows the number 120, which is the number of puffs in the inhaler. If you have not used your inhaler for a week or longer, spray two puffs of medicine into the air.

### Using your inhaler

Before using your inhaler, it is important to start by breathing as slowly as possible.

1. Stand or sit upright when using your inhaler.
2. Remove the cap from the mouthpiece (as described in step 1 of: "Testing your inhaler"). Check the inside and outside of the mouthpiece to ensure it is clean and free of any loose objects.
3. Shake the inhaler 4 or 5 times to ensure any loose objects are removed and the contents are evenly mixed..
4. Hold the inhaler upright, with your thumb at the base, behind the mouthpiece. Breathe out well as far as you can..
5. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite it..
6. Breathe in slowly and deeply through your mouth. Immediately after you start to inhale, press down firmly on the top of the canister to release a puff of medicine into your mouth while continuing to inhale steadily and deeply.
7. Hold your breath, remove the inhaler from your mouth, and take your finger off the top of the inhaler. Hold your breath for a few seconds or as long as you can without much effort.
8. Wait about half a minute between each puff of medication and then repeat steps 3 through 7.
9. Rinse your mouth with water and spit it out and/or brush your teeth afterward. This can help prevent thrush (a fungal infection in the mouth) and hoarseness.
10. Always replace the protective cap over the mouthpiece after use to keep it dust-free. If the mouthpiece cap is properly placed, it will click into place. If the cap does not click into place, turn it the other way and try again. Do not use excessive force.

Do not rush steps 4, 5, 6, and 7. It is important to breathe in as slowly as possible just before using the inhaler. The first few times you use the inhaler, you should do this while standing in front of a mirror. If you see "mist" appearing at the top of the inhaler or at the sides of your mouth, you need to start again from step 3.

If you find it difficult to use the inhaler, your doctor or another healthcare provider may recommend using a spacer such as the Volumatic® or the AeroChamber Plus® in combination with your inhaler. Your doctor, pharmacist, or another healthcare provider should demonstrate how to use the spacer with your inhaler, how to maintain the spacer, and will answer any questions you may have. It is important that when you use a spacer with your inhaler, you do not stop or reduce its use without first discussing it with your doctor. It is also important that you do not change the type of spacer you use without discussing it with your doctor. If you stop using the spacer or change the type of spacer you use, your doctor may need to adjust the medication dosage required to keep your asthma under control.

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. Place the two index fingers on top of the inhaler and both thumbs at the bottom, behind the mouthpiece.

You should remember to replace your inhaler as soon as the dose indicator shows the number 40 and the color of the dose indicator changes from green to red. Stop using the inhaler when the dose indicator shows 0, as the puffs remaining in the canister may not be sufficient for a full dose. Never attempt to change the numbers on the dose indicator or detach the dose indicator from the canister. The position of the counter cannot be changed and the counter is permanently attached to the canister.

#### Cleaning your inhaler

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

To clean your inhaler:

- remove the mouthpiece cover
- never remove the metal canister from the plastic holder
- clean the inside and outside of the mouthpiece and the plastic holder with a dry cloth or tissue
- replace the mouthpiece cover. It will click into place if properly positioned. If it does not click into place, turn the cover the other way and try again. Do not use excessive force.

Do not place the metal canister in water.

#### Have you used too much of this medicine?

It is important that you use the inhaler according to the instructions. If you accidentally inhale a higher dose than recommended, tell your doctor or pharmacist. You may notice that you have a faster heartbeat than normal and feel shaky. You may also experience dizziness, headache, muscle weakness, and joint pain.

If you have used higher doses for a long period, you should ask your doctor or pharmacist for advice. Higher doses of this medicine can reduce the amount of steroid hormones produced by the adrenal glands.

#### Have you forgotten to use this medicine?

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 this medicine

It is very important that you use this medicine every day according to the instructions. Continue until your doctor tells you to stop. Do not stop suddenly and do not suddenly reduce your dosage of this medicine. This may cause your breathing problem to worsen.

Moreover, suddenly stopping the use of this medicine or reducing your dosage of this medicine (in very rare cases) can cause problems with your adrenal glands (adrenal insufficiency). This can sometimes cause side effects. These side effects may include:

- stomach pain
- fatigue and loss of appetite, feeling unwell
- nausea and diarrhea
- weight loss
- headache or feeling drowsy
- low blood sugar levels
- low blood pressure and uncontrollable body shakes, often as part of a seizure.

When your body is under stress such as with fever, trauma (such as a car accident), infection, or surgery, the adrenal insufficiency may worsen and you may experience one of the side effects listed above. If you experience side effects, contact your doctor or pharmacist. To prevent these symptoms, your doctor may prescribe extra corticosteroids in tablet form (such as prednisolone).

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. To minimize the chance of side effects, your doctor will prescribe the lowest possible dose of this medicine to control your asthma.

Allergic reactions: you may notice that your breathing suddenly worsens immediately after using this medicine. You may experience severe wheezing and coughing or shortness of breath. You may also experience itching, 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 weak or light-headed (this can lead to fainting or loss of consciousness). If you experience any of these side effects or if they occur suddenly after using this medicine, stop using it and tell your doctor immediately. Allergic reactions sometimes occur with this medicine (in less than 1 in 100 users).

Other side effects are listed below.

Very common (occur in more than 1 in 10 users)

- headache – this usually improves over the course of treatment
- an increase in the number of colds has been reported in patients with COPD.

Common (occur in less than 1 in 10 users)

thrush (painful, cream-colored, thickened patches) in the mouth and throat. Additionally, a sore tongue, hoarse voice, and throat irritation. It may help to rinse your mouth with water immediately after each dose of your medication and spit it out immediately and/or brush your teeth. Your doctor may prescribe an antifungal medication to treat your thrush  
painful, swollen joints and muscle pain  
muscle cramps.

The following side effects have also been reported in patients with chronic lung disease with persistent narrowing of the airways making breathing more difficult (COPD):

pneumonia (lung infection). Tell your doctor if you experience any of the following symptoms while using this medicine – these may be symptoms of pneumonia:

- increased mucus production
- change in the color of the mucus
- fever
- chills
- more frequent coughing
- increased difficulty breathing

bruising and bone fractures

inflammation of the sinuses (feeling of pressure or fullness in the nose, cheeks, and behind the eyes, sometimes with a throbbing pain)

a lower amount of potassium in the blood (you may experience an irregular heartbeat, muscle weakness, cramps).

Sometimes (occur in less than 1 in 100 users)

increased amount of sugar (glucose) in your blood (hyperglycemia). If you have diabetes, you may need to monitor your blood sugar levels more frequently and your usual diabetes medication may need to be adjusted

clouding of the lens of the eye (cataract)

accelerated heartbeat (tachycardia)

involuntary shaking (tremor) and a rapid or irregular heartbeat (palpitations). These side effects are usually harmless and decrease over the course of treatment

chest pain

feeling anxious (this usually occurs in children)

disturbed sleep

allergic skin rash (rash).

Rare (occur in less than 1 in 1,000 users)

breathing difficulties or wheezing that worsens after using this medicine. If this happens, stop using the inhaler with this medicine. Use your fast-acting emergency inhaler to help your breathing and inform your doctor immediately.

this medicine can affect the normal production of steroid hormone in the body, especially when you have used high doses for a long time. The effects are:

- delayed growth in children and adolescents up to 18 years
- thinning of the bones
- increased eye pressure (glaucoma)
- weight gain
- moon face (Cushing's syndrome).

Your doctor will regularly monitor you for these side effects and ensure that you use the lowest possible dose of this medicine to control your asthma.

behavioral changes, such as being unusually active and irritable (these side effects usually occur in children).

heart rhythm disorder (arrhythmia). Inform your doctor, but do not stop using this medicine unless your doctor advises you to.

a fungal infection of the esophagus, which may cause difficulty swallowing.

Not known (cannot be determined from the available data)

depression or aggression. These side effects occur more frequently in children

Blurred vision.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to any possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb. Website:

www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

## 5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the label and the box after "Exp.". It includes a month and a year. The last day of that month is the expiry date.

Store below 25°C.

Keep the canister in the outer packaging to protect from light.

The canister contains a pressurized liquid.

Do not pierce, break, or burn the canister, even if it seems empty.

As with most inhalation medicines in an aerosol (which is pressurized), the therapeutic effect of the medicine may decrease when the canister is cold.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

## 6. Contents of the packaging and other information

What substances are in this medicine?

AirFluSal Aerosol 25/125 micrograms, aerosol, suspension

The active substances in this medicine are salmeterol and fluticasone propionate. Each measured dose of this medicine delivers 25 micrograms of salmeterol (as salmeterol xinafoate) and 125 micrograms of fluticasone propionate.

The other substance in this medicine is norflurane (HFA 134a) as a propellant.

AirFluSal Aerosol 25/250 micrograms, aerosol, suspension

The active substances in this medicine are salmeterol and fluticasone propionate. Each measured dose of this medicine delivers 25 micrograms of salmeterol (as salmeterol xinafoate) and 250 micrograms of fluticasone propionate.

The other ingredient in this medicine is norflurane (HFA 134a) as a propellant.

This medicine contains fluorinated greenhouse gases.

Each inhaler contains 12.5 grams of HFA 134a. This is equivalent to 0.0179 tons of CO<sub>2</sub> (global warming potential GWP = 1430).

What does AirFluSal Aerosol look like and what is in a package?

The inhaler consists of an aluminum canister (plasma FCP coated aerosol) with a suitable metering valve and a polypropylene holder with cap and dose indicator packed in a cardboard box.

The canister contains a white, homogeneous suspension.

Each canister contains 120 inhalations.

Package size:

1 inhaler x 120 inhalations.

Marketing authorization holder and manufacturer Marketing authorization holder Sandoz B.V.

Hospitaaldreef 29

1315 RC Almere

Netherlands

Manufacturer

Salutas Pharma GmbH

Otto-von-Guericke Allee 1

39179 Barleben

Germany

Lek Pharmaceuticals d.d.

Verovškova ulica 57

1526 Ljubljana

Slovenia

Registered under:

AirFluSal Aerosol 25/125 microgram, aerosol, suspension: RVG 118836

AirFluSal Aerosol 25/250 microgram, aerosol, suspension: RVG 118837

This medicine is registered in EEA member states under the following names:

Netherlands AirFluSal Aerosol 25/125 microgram, aerosol, suspension

AirFluSal Aerosol 25/250 microgram, aerosol, suspension

This leaflet was last approved in May 2025.