

AirFluSal® Forspiro® 50 microgram/500 microgram per actuation inhalation powder, pre-dispensed

(salmeterol xinafoate/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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What AirFluSal Forspiro is and what it is used for
2. What you need to know before you use AirFluSal Forspiro
3. How to use AirFluSal Forspiro
4. Possible side effects
5. How to store AirFluSal Forspiro
6. Contents of the pack and other information

1. What AirFluSal Forspiro is and what it is used for

AirFluSal Forspiro 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.

Your doctor has prescribed this medicine for the treatment of either:

- Severe asthma, to help prevent attacks of breathlessness and wheeziness, or
- Chronic obstructive pulmonary disease (COPD), to reduce the number of flare ups of symptoms.

You must use AirFluSal Forspiro every day, as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD.

AirFluSal Forspiro helps to stop breathlessness and wheeziness coming on. However, AirFluSal Forspiro should not be used to relieve an 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.

AirFluSal Forspiro should only be used to treat severe asthma in adults aged 18 years and older and adults with COPD.

AirFluSal Forspiro is NOT indicated for use in children 12 years of age and younger or adolescents 13 to 17 years of age.

2. What you need to know before you use AirFluSal Forspiro

Do not use AirFluSal Forspiro

- if you are allergic (**hypersensitive**) to salmeterol or fluticasone propionate or to the other ingredient in this medicine (see section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using AirFluSal Forspiro if you have:

- heart disease, including an irregular or fast heartbeat
- overactive thyroid gland
- high blood pressure
- diabetes mellitus (AirFluSal Forspiro may increase your blood sugar)
 - low potassium in your blood
- tuberculosis (TB) now or have had in the past or have other lung infections

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

Children and adolescents

This medicine should not be used in children or adolescents under the age of 18 years.

Other medicines and AirFluSal Forspiro

Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines. This includes other medicines for asthma or COPD, any other inhalers or any medicines obtained without a prescription. AirFluSal Forspiro may not be suitable to be taken with some other medicines. Tell your doctor if you are taking any of the following medicines, before starting to use

AirFluSal Forspiro:

- **Beta-blockers** (such as atenolol, propranolol, sotalol). Beta blockers are mostly used for high blood pressure or heart conditions such as angina.
- **Medicines to treat infections** (such as 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 side effects with AirFluSal Forspiro, including irregular heartbeats, or may make side effects worse.
- **Medicines to treat viruses** including some medicines for HIV (such as ritonavir or cobicistat). Your doctor may wish to monitor you carefully if you are taking these medicines.
- **Corticosteroids** (by mouth or by injection). Recent use of these medicines might increase the risk of AirFluSal Forspiro affecting your adrenal glands.
- **Diuretics**, also known as ‘water tablets’ used to treat high blood pressure.
- Other **bronchodilators** (such as salbutamol).
- **Xanthine** medicines such as aminophylline and theophylline. These are often used to treat asthma.

Pregnancy and breast-feeding

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

It is not known whether this medicine can pass into breast milk. If you are breast-feeding, check with your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

AirFluSal Forspiro is not likely to affect your ability to drive or use machines.

AirFluSal Forspiro contains lactose

AirFluSal Forspiro contains 11.95 mg lactose in each dose. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. Lactose is a type of sugar found in milk and may contain small amounts of milk proteins which may cause allergic reactions in those with severe hypersensitivity or allergy to milk protein. If you have been told by your doctor that you have an intolerance or allergy to lactose, other sugars or milk, contact your doctor before taking this medicine.

3. How to use AirFluSal Forspiro

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

- Use your AirFluSal Forspiro 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 AirFluSal Forspiro or reduce the dose of AirFluSal Forspiro

- without talking to your doctor first.
- AirFluSal Forspiro should be inhaled through the mouth into the lungs.

The recommended dose is:

Severe asthma in adults 18 years of age and older:

One inhalation twice a day

Chronic obstructive pulmonary disease (COPD):

One inhalation twice a day

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

Your doctor will help you to manage your asthma and will adjust the dose of this medicine to the lowest dose that controls your asthma. If your doctor feels that you need a lower dose than is available from your AirFluSal Forspiro, your doctor may prescribe an alternative inhaler containing the same active substances as your AirFluSal Forspiro but with a lower dose of the corticosteroid. However, do not change the number of inhalations your doctor has prescribed without talking to your doctor first.

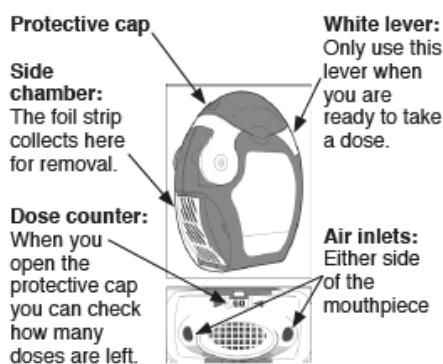
Use in children and adolescents

This medicine is **not** for use in children and adolescents less than 18 years of age.

If your asthma or breathing gets worse tell your doctor straight away. If you feel more wheezy, your chest feels tight more often or you need to use more of your fast-acting ‘reliever’ medicine your chest condition may be getting worse and you could become seriously ill. You should continue to take AirFluSal Forspiro but do not increase the number of puffs you take. See your doctor at once as you may need additional treatment.

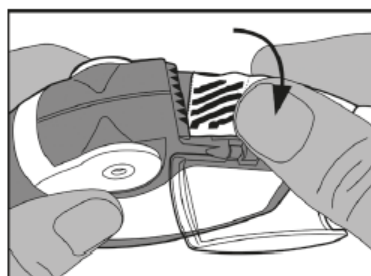
Instructions for use

Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check on how you use it from time to time. If you do not use the inhaler properly or as prescribed, the medicine might not help your asthma or COPD as it should. The inhaler contains 60 doses of powder medication in a coiled strip of foil. It has a dose counter which shows you how many doses you have remaining counting down from 60 to 0. When you have reached the last 10 doses the numbers will be on a red background. The inhaler is not refillable – please dispose of the inhaler when it is empty and replace it with a new one.



Before using the inhaler

- Open the transparent side chamber door.
- Remove the foil strip from the side chamber by carefully tearing away the full length of strip against the ‘teeth’ of the side chamber as shown below. **Do not pull or tug** on the strip.

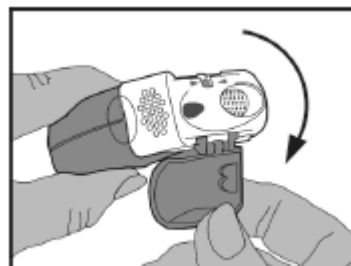


- Close the side chamber door and dispose of the used strip.
- Important:** As you use the inhaler the side chamber will gradually fill up with used strip. The foil strips with **black bars don’t contain medication**. Eventually the numbered sections of the strip will appear in the side chamber. **Do not let more than 3 sections of foil strip build up** in the side chamber as they may cause the inhaler to jam. Tear the strip away carefully as shown above, and dispose of it safely.

Using the inhaler

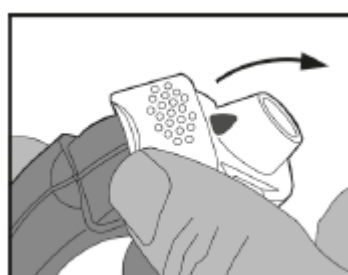
Hold the inhaler in your hands as seen in the pictures.

1. Open

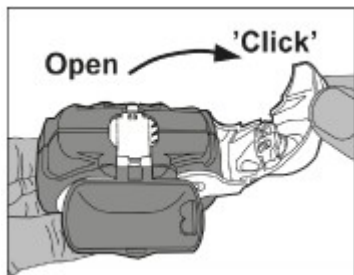


- Open the protective cap downwards to reveal the mouthpiece.
- Check the dose counter to see how many doses are left.

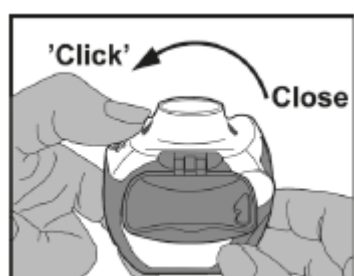
2. Prepare the dose



- **Lift up the edge of the white lever.** Make sure the side chamber is closed.
- Remember:** Only operate the white lever when you are ready to inhale a dose of your medication. If you play with the white lever, you will waste doses.



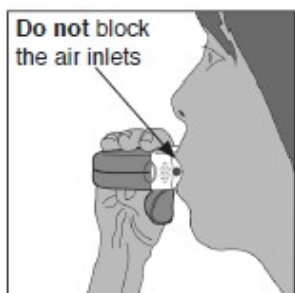
- **Open:** Move the white lever fully over as far as it will go and **until it clicks**. This action moves a new dose into position with the number at the top.



- **Close:** Afterwards close the white lever fully so that it **clicks** back into its original position. The inhaler is now ready for immediate use.

3. Inhale

- Away from the inhaler mouthpiece, breathe out as much as is comfortable. **Never breathe directly into** the inhaler as this could affect the dose.
- Hold the inhaler level with the **protective cap pointing downwards**.
- Place the mouthpiece between your teeth and close your lips firmly around it. However do not bite the mouthpiece.
- **Breathe** in steadily and **deeply** through the inhaler, not through your nose.



- Remove the inhaler from your mouth and **hold your breath for 5-10 seconds** or as long as you can without causing discomfort.
- Afterwards, breathe out slowly, **but not into the inhaler**.
 - Close the protective cap over the mouthpiece.
 - Rinse your mouth with water and spit it out and/or brush your teeth. This may help to prevent you from getting fungal infections, such as thrush in the mouth and/or help to prevent you from becoming hoarse.

Cleaning

- Wipe the outside of the mouthpiece with a clean, dry cloth or tissue if necessary.
- Do not attempt to take the inhaler apart to clean it or for any other purpose.
- Do not use water or wet wipes to clean the inhaler parts as dampness can affect the dose.
- Never insert a pin or other sharp objects into the mouthpiece, or any other part, as this could damage the inhaler.

If you use more AirFluSal Forspiro than you should

It is important to use the inhaler as instructed. If you accidentally take more doses than are recommended, talk to your doctor, pharmacist or nurse. 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 too many doses of AirFluSal Forspiro for a long time, you should talk to your doctor, pharmacist or nurse for advice. This is because using too much AirFluSal Forspiro may reduce the amount of steroid hormones produced by your adrenal glands.

If you forget to use AirFluSal Forspiro

If you forget to use your inhaler, take your next inhalation when it is due. Do not take a double dose to make up for a forgotten dose.

If you stop using AirFluSal Forspiro

It is very important that you take your AirFluSal Forspiro every day as directed. **Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of AirFluSal Forspiro.** This could make your breathing worse. In addition, if you suddenly stop using AirFluSal Forspiro or reduce your dose of AirFluSal Forspiro, this may (very rarely) cause you to have problems with your adrenal glands (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 or injury), 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, pharmacist or nurse. To prevent these symptoms, 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, pharmacist or nurse.

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 this combination of drugs to control your asthma or COPD.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using AirFluSal Forspiro. 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 AirFluSal Forspiro, stop using AirFluSal Forspiro and tell your doctor straight away.** Allergic reactions to AirFluSal Forspiro 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 chronic obstructive pulmonary disease (COPD).

Common, may affect up to 1 in 10 people

- Thrush (sore, creamy-yellow, raised patches) in the mouth and throat. Also sore tongue, 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 medicine to treat the thrush.
- Aching, swollen joints and muscle pain
- Muscle cramps
- Pneumonia and bronchitis (infection of the lung) in patients with COPD
Tell your doctor if you have any of the following while taking AirFluSal Forspiro, they could be symptoms of a lung infection:
 - increase in mucous production
 - change in mucous colour
 - fever
 - chills
 - increased cough
 - increased breathing difficulties

- Bruising and fractures
- Inflammation of sinuses (sinusitis, a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache).
- A reduction of the amount of potassium in the blood (you may get uneven heartbeats, muscle weakness, cramp).

Uncommon, may affect up to 1 in 100 people

- Increase 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.
- Cloudy lens in the eye (cataract)
- Very fast heartbeat (tachycardia)
- Feeling shaky (tremor) with fast or uneven heartbeat (palpitation). These are usually harmless and get less as treatment continues.
- Chest pain
- Feeling worried (although this effect occurs mainly in children when prescribed this combination of drugs but in a lower strength).
- Disturbed sleep
- Allergic skin rash

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

- **Breathing difficulties or wheezing that gets worse straight after using AirFluSal Forspiro. If this happens stop using your AirFluSal Forspiro inhaler.** Use your fast-acting 'reliever' inhaler to help your breathing **and tell your doctor straight away.**

- AirFluSal Forspiro 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:

- Thinning of the bones
- Increased eye pressure (glaucoma)
- Weight gain
- Rounded, moon shaped face (Cushing's Syndrome)
- Slowing of growth in children and adolescents.

Your doctor will check you regularly for any of these side effects and make sure you are taking the lowest dose of this combination of drugs to control your disease.

- Behavioural changes, such as being unusually active and irritable (although these effects occur mainly in children when prescribed this combination of drugs but in a lower strength).
- Uneven or irregular heartbeat or an extra heartbeat (arrhythmias).
Tell your doctor, but do not stop using AirFluSal Forspiro unless the doctor tells you to stop.
- Fungal infection in the oesophagus (food canal), which might cause difficulties in swallowing.

Frequency not known, but may also occur

- Depression or aggression (although these effects occur mainly in children when prescribed this combination of drugs but in a lower strength).
- Blurred vision.

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 via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store AirFluSal Forspiro

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

Do not store above 25°C.

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.

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 AirFluSal Forspiro contains

The active substances are salmeterol and fluticasone propionate.

- Each metered dose provides 50 micrograms of salmeterol (as xinafoate) and 500 micrograms of fluticasone propionate.
- The other ingredient is lactose monohydrate. – see the end of section 2, under the sub-heading *AirFluSal Forspiro contains lactose.*

What AirFluSal Forspiro looks like and contents of the pack

- A purple plastic dry-powder inhalation device holding 60 aluminium blisters containing a white inhalation powder.
- Each dose is pre-dispensed in pack size 60.

Manufacturers

Aeropharm GmbH, Francois-Mitterrand-Allee 1, 07407 Rudolstadt, Germany.

Lek Pharmaceuticls d.d., Verovskova 57, 1526 Ljubljana, Slovenia.

Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Procured from within the EU and repackaged by PL holder PilsCo Ltd, 10-16 Colvilles Place, East Kilbride, G75 0SN.

PL 39467/0327 AirFluSal® Forspiro® 50 microgram/500 microgram per actuation inhalation powder, pre-dispensed

POM

Blind or partially sighted?

Is this leaflet hard to see or read?

Call 0800 198 5000 to obtain the leaflet in a format suitable for you.

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