

## Package leaflet: Information for the user

### AirFluSal® Forspiro® 50 microgram/250 microgram/dose, inhalation powder, predispensed

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 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® is used to treat:

- asthma.

This medicine contains two active substances.

- Salmeterol: a long-acting substance that widens the airways
- Fluticasone: a corticosteroid which reduces swelling and inflammation in the lungs.

#### **2. What you need to know before you use AirFluSal® Forspiro®**

##### **Do not use AirFluSal® Forspiro®**

- if you are **allergic** to salmeterol, fluticasone or to the other ingredient of this medicine (listed in section 6).

##### **Warnings and precautions**

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

- heart disease, including an irregular or fast heartbeat
- overactive thyroid gland
- high blood pressure
- diabetes mellitus
- low potassium in your blood
- tuberculosis now or in the past, or other lung infections.

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

AirFluSal<sup>®</sup> Forspiro<sup>®</sup> prevents the onset of breathlessness and wheezing. Please note that it does not work when you are already breathless or wheezy.

If such a **breathlessness attack** occurs, you need to use a medicine which quickly widens the airways, such as salbutamol.

**Inform your doctor immediately if your asthma or breathing gets worse. You may find that:**

- you feel more wheezy
- your chest feels tight more often
- you need to use more of your fast acting airway widening inhaler.

Continue to use AirFluSal<sup>®</sup> Forspiro<sup>®</sup> if any of these happen, but do not increase the number of inhalations. Your chest condition may be getting worse and you could become seriously ill. Talk to your doctor as you may need additional treatment.

### **Children and adolescents**

AirFluSal<sup>®</sup> Forspiro<sup>®</sup> should not be used in children under the age of 12 years.

### **Other medicines and AirFluSal<sup>®</sup> Forspiro<sup>®</sup>**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The following medicines can influence or be influenced by AirFluSal<sup>®</sup> Forspiro<sup>®</sup> :

- medicines to treat high blood pressure, heart or other illnesses, with active substance names ending with “olol” (beta-blockers), such as atenolol, propranolol and sotalol
- 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.
- medicines to treat infections, such as ketoconazole, itraconazole and erythromycin
- corticosteroids taken by the mouth or injected: medicines to treat inflammation or prevent organ transplant rejection
- 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, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will assess whether you can take AirFluSal<sup>®</sup> Forspiro<sup>®</sup> during this time.

### **Driving and using machines**

AirFluSal<sup>®</sup> Forspiro<sup>®</sup> is unlikely to impair your ability to drive or operate machinery.

### **AirFluSal<sup>®</sup> Forspiro<sup>®</sup> contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant.

### **3. How to use AirFluSal® Forspiro®**

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

- **Asthma**

The recommended dose **for adults and children from 12 years** is:

One inhalation twice daily

Your doctor will want to regularly check your asthma symptoms.

If your symptoms become controlled using AirFluSal® Forspiro® twice daily, your doctor may reduce your dose to once daily:

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

#### **Method of use**

Use AirFluSal® Forspiro® every day as prescribed by your doctor, preferably **right before mealtimes** in the morning and/or in the evening.

After use, rinse your mouth with water.

Not using AirFluSal® Forspiro® properly or as prescribed may worsen your breathing difficulties. For optimal therapy, you must use AirFluSal® Forspiro® daily, even if you don't have any symptoms.

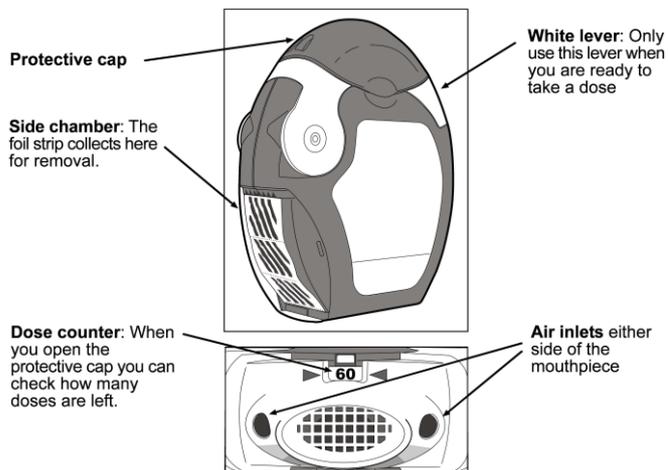
#### **Instructions for use**

Your doctor, nurse or pharmacist should demonstrate how to use the inhaler and should check your use regularly.

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.

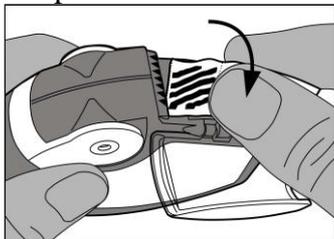
When you have reached the last 10 doses the numbers will be on a red background.

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:**

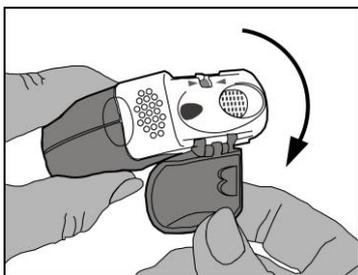
As you use the inhaler the side chamber will gradually fill up with used strip. The foil strips with **black bars don’t contain medication**. Eventually the numbered sections of the strip will appear in the side chamber.

**Do not let more than 2 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.

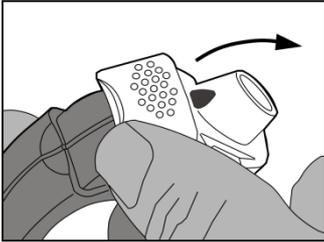
#### 1. Open



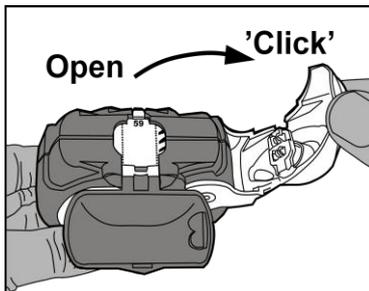
- **Open** the protective **cap downwards** to reveal the mouthpiece.

- Check the dose counter to see how many doses are left.

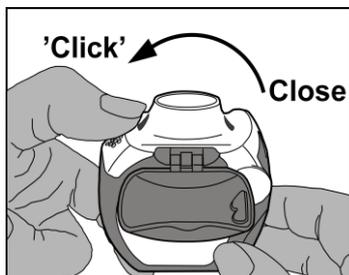
## 2. Prepare the dose



- **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.



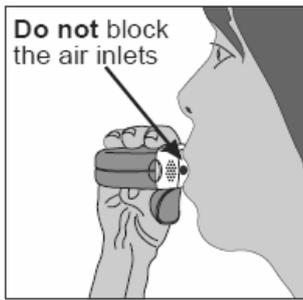
- **Open:** Move the **white lever fully over** as far as it will go and **until it clicks**. This action moves a new dose into position with the number at the top.



- **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**.
- Close your lips firmly around 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. This may help to prevent you from getting fungal infection in the mouth and becoming hoarse.

### **Cleaning**

- Wipe the outside of the mouthpiece with a clean, dry 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**

Contact your doctor or pharmacist.

Overdose symptoms are:

- dizziness
- headache
- rapid heartbeat
- muscle weakness
- aching joints
- feeling shaky.

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 AirFluSal® Forspiro® may reduce the amount of steroid hormones produced by the adrenal gland.

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

### **If you forget to use AirFluSal® Forspiro®**

Do not take a double dose to make up for a forgotten dose. Use your next dose when it is due.

### **If you stop using AirFluSal® Forspiro®**

Do not stop or suddenly reduce your dose of AirFluSal® Forspiro® without your doctor's permission as this could cause your breathing problems to worsen and very rarely side effects could occur. These include:

- 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.

Very rarely, if you get an infection or at times of extreme stress (such as after a serious accident or if you have surgery), you may get similar side effects. To prevent these symptoms occurring, your doctor may prescribe extra corticosteroids (like 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.

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

#### Other side effects can occur with the following frequencies:

**Very Common**, may affect more than 1 in 10 people

- headache  
This usually gets better as treatment continues.
- increased number of colds 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 each inhalation 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 (infection of the lung)  
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 throughout the body
- inflammation of the sinuses
- low potassium level in the blood (you may get an uneven heartbeat, muscle weakness and/or cramp).

**Uncommon**, may affect up to 1 in 100 people

- very fast heartbeat (tachycardia)
- feeling shaky and a fast or uneven heartbeat (palpitation)  
This is usually harmless and decreases during therapy.
- feeling worried  
This effect mainly occurs in children.
- increased blood sugar level  
If you have diabetes, more frequent blood sugar monitoring and possible adjustment of your diabetic medicines may be required.
- disturbed sleep
- chest pain
- clouding of the eye lens (cataract)
- 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®.  
**Stop using** your AirFluSal® Forspiro® and use your fast-acting airway widening inhaler to help your breathing. **Tell your doctor straight away.**
- abnormal production of certain hormones, particularly when using this medicine in high doses over a long time  
Signs are:
  - slowing of growth in children and adolescents
  - thinning of the bones
  - increased eye pressure (glaucoma)
  - weight gain
  - rounded, moon shaped face (Cushing's Syndrome).
 Your doctor will check you regularly for any of these side effects, ensuring you are on the lowest dose possible.
- behavioural changes, such as being unusually active and irritable  
These effects mainly occur in children.
- irregular heartbeat or heart gives an extra beat  
Tell your doctor, but do not stop using AirFluSal® Forspiro® unless told to do so.
- a fungal infection in the oesophagus (gullet), which might cause difficulties in swallowing.

**Frequency not known**, but may also occur

- depression or aggression  
These effects mainly 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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). 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**

AirFluSal® Forspiro® 50/250 microgram/dose inhalation powder, predispensed:

- The active substances are salmeterol and fluticasone. Each metered dose of AirFluSal® Forspiro® provides 50 micrograms of salmeterol (as salmeterol xinafoate) and 250 micrograms of fluticasone propionate.  
Corresponding with a delivered dose of:  
45 micrograms of Salmeterol (as salmeterol xinafoate) and 233 micrograms of fluticasone propionate.
- The other ingredient is lactose monohydrate.

#### **What AirFluSal® Forspiro® looks like and contents of the pack**

- In the purple plastic dry-powder inhalation device, 60 doses of powder blend are contained in an aluminium blister.
- Each dose is pre-dispensed.
- Pack sizes:

1, 2, 3, 4 or 6 devices containing 60 doses

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

### **Manufacturer**

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

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Croatia:	AirFluSal Forspiro 50 mikrograma + 250 mikrograma u jednoj dozi, prašak inhalata, dozirani
Czech Republic:	AIRFLUSAN FORSPIRO 50 MIKROGRAMŮ/250 MIKROGRAMŮ
Estonia:	AirFluSal Forspiro
Greece:	AirFluSal Forspiro
Ireland:	AirFluSal <sup>®</sup> Forspiro <sup>®</sup> 50 microgram/250 microgram/dose, inhalation powder, predispensed
Latvia:	AirFluSal Forspiro 50/250 mikrogrami/devā pulveris inhalācijām, dozēts
Lithuania:	AirFluSal Forspiro 50/250 mikrogramų/dozėje dozuoti įkvepiamieji milteliai
Slovakia:	Airflusal Forspiro 50 mikrogramov/250 mikrogramov
Slovenia:	Airflusan Forspiro 50 mikrogramov/250 mikrogramov/odmerek prašek zainhaliranje, odmerjeni
Sweden:	Molduo Forspiro, 50 mikrogram/250 mikrogram inhalationspulver

**This leaflet was last revised in 08/2017.**