

PACKAGE LEAFLET

Package leaflet: Information for the patient

Sametec Airmaster 50 microgram/100 microgram/ dose inhalation powder, pre-dispensed
Sametec Airmaster 50 microgram/250 microgram/ dose inhalation powder, pre-dispensed
Sametec Airmaster 50 microgram/500 microgram/ dose inhalation powder, pre-dispensed
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, 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 Sametec Airmaster is and what it is used for
2. What you need to know before you use Sametec Airmaster
3. How to use Sametec Airmaster
4. Possible side effects
5. How to store Sametec Airmaster
6. Contents of the pack and other information

1. What Sametec Airmaster is and what it is used for

Sametec Airmaster 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.

Sametec Airmaster is used to treat adults and adolescents 12 years of age and older.

The doctor has prescribed this medicine to help prevent breathing problems such as:

- Asthma
- or
- Chronic Obstructive Pulmonary Disease (COPD). Sametec Airmaster, at a dose of 50/500 micrograms, reduces the number of flare ups of COPD symptoms.

You must use Sametec Airmaster everyday as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD.

Sametec Airmaster helps to prevent breathlessness and wheeziness. However, Sametec Airmaster should not be used to relieve an attack of breathlessness or wheezing. If you are experiencing a sudden attack of breathlessness or wheezing, 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 Sametec Airmaster

Do not use Sametec Airmaster

If you are allergic to salmeterol, fluticasone propionate or to the other ingredient lactose monohydrate.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Sametec Airmaster if you have:

- Heart disease, including an irregular or fast heart beat

- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (Sametec Airmaster 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

This medicine should not be used in children under 12 years of age.

Other medicines and Sametec Airmaster

Tell your doctor or pharmacist if you are taking or, have recently taken or might take any other medicines. This is because Sametec Airmaster 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 Sametec Airmaster.

- Beta blockers (such as atenolol, propranolol and 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) including some medicines for HIV treatment (such as ritonavir, cobicistat containing products). 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 Sametec Airmaster, 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 Sametec Airmaster 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 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

Sametec Airmaster is not likely to affect your ability to drive or use machines.

Sametec Airmaster contains lactose

Sametec Airmaster contains approximately 13 milligrams of lactose monohydrate in each dose. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions. Sametec

3. How to use Sametec Airmaster

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

The recommended dose is:

For asthma

Adults and adolescents aged 12 years of age and older

- Sametec Airmaster 50/100 - One inhalation twice a day
- Sametec Airmaster 50/250 - One inhalation twice a day
- Sametec Airmaster 50/500 - One inhalation twice a day

For adults with Chronic Obstructive Pulmonary Disease (COPD)

- Sametec Airmaster 50/500 - One inhalation twice a day

Your symptoms may become well controlled using Sametec Airmaster 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 inhalations to take and how often to take your medicine.

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

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 Sametec Airmaster, but do not increase the number of puffs you take. The chest condition may be getting worse and you could become seriously ill. See your doctor as you may need additional treatment.

Instructions for use.

- **Sametec Airmaster may be different to inhalers you have used in the past, therefore it is very important that you use it properly. Your doctor, nurse or pharmacist should show you how to use your inhaler. This training is important to ensure you receive the dose you require. If you have not received this training please ask your doctor, nurse or pharmacist to show you how to use your inhaler properly, especially before you use it for the first time.**

They should also check how you use it from time to time to ensure that you are using the device properly and as prescribed. Not using the Sametec Airmaster properly or as prescribed may mean that it will not help your asthma **or COPD** as it should.

- The device holds blisters containing salmeterol/fluticasone propionate as a powder.
- There is a counter on top of the device which tells you how many doses are left. It counts down to 0. The numbers 5 to 0 will appear in red to warn you when there are only a few doses left. Once the counter shows 0, your inhaler is empty.

Using your Inhaler

1. To open your inhaler, hold the inhaler in one hand in a flat level position. Depress the red button with the thumb (*see Figure 1*) and rotate the light pink (for 50/100 microgram strength), pink (for 50/250 microgram strength) or mauve (for 50/500 microgram strength) mouthpiece cover away from you with the thumb of your other hand as far as it will go until you will hear a "click" (*see Figure 2*). This will open a small hole in the mouthpiece, and places a dose of your medicine in the mouthpiece.

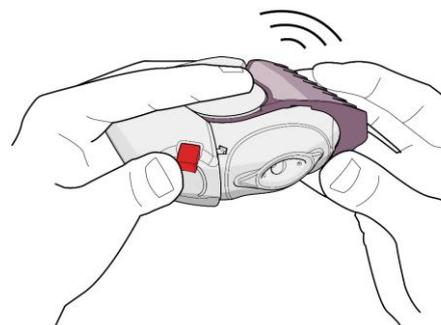
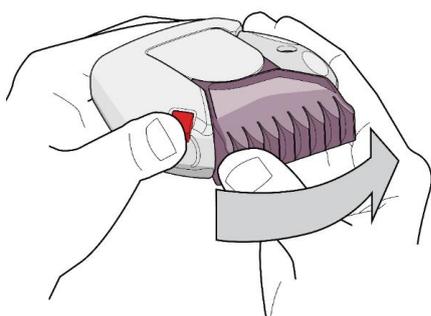


Figure 1

Figure 2

Note, every time the mouthpiece cover is opened with a “click”, a blister is opened inside, and the powder made ready for you to inhale therefore,. do not open the mouthpiece cover if you do not need to take your medicine as this opens the blisters and wastes medicine.

2. Hold the inhaler away from your mouth, breathe out as far as is comfortable. Do not breathe into your inhaler.
3. Put the mouthpiece to your lips (*see Figure 3*). Breathe in steadily and deeply through the inhaler, **not through your nose**.
Remove the inhaler from your mouth.
Hold your breath for about 10 seconds, or for as long as is comfortable.
Breathe out slowly.

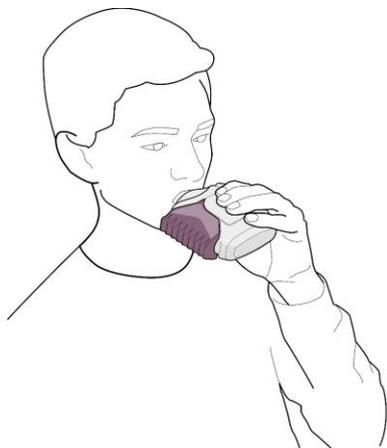


Figure 3

The inhaler delivers your dose of medicine as a very fine powder. You may or may not taste or feel the powder. **Do not use extra dose from the Inhaler if you do not feel or taste the medicine.**

4. Close the inhaler to maintain cleanliness, by rotating the light pink (for 50/100 microgram strength), pink (for 50/250 microgram strength) or mauve (for 50/500 microgram strength) mouthpiece cover back towards you as far as it will go. You will hear a “click” (see Figure 4). The mouthpiece cover has now been returned to its original position and reset. The inhaler is now ready for you to take your next scheduled dose
5. 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.

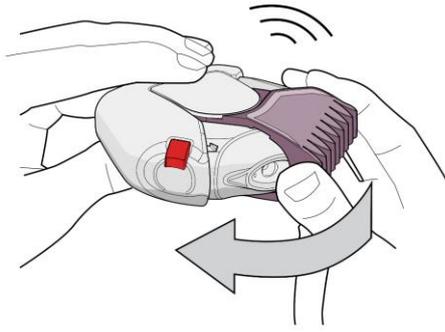


Figure 4

Cleaning your inhaler

Keep your inhaler dry and clean.

If necessary, you may wipe the mouthpiece of your inhaler with a dry cloth or tissue.

If you use more Sametec Airmaster than you should

It is important to use the inhaler as instructed. If you accidentally take more doses than is 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 of Sametec Airmaster for a long time, you should talk to your doctor or pharmacist for advice. This is because using larger doses of Sametec Airmaster may reduce the amount of steroid hormones produced by your adrenal glands.

If you forget to use Sametec Airmaster

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 Sametec Airmaster

It is very important that you take your Sametec Airmaster every day as directed. **Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of Sametec Airmaster.**

This could make your breathing worse.

In addition, if you suddenly stop taking Sametec Airmaster or reduce your dose of Sametec Airmaster 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 an 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 or pharmacist. 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 medicines to control your asthma or COPD.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Sametec Airmaster. 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 Sametec Airmaster, stop using Sametec Airmaster and tell your doctor straight away.** Allergic reactions to Sametec Airmaster are uncommon (they may affect up to 1 in 100 people).

Pneumonia (infection of the lung) in COPD patients. (Common side effect)

Tell your doctor if you have any of the following while taking Sametec Airmaster as these could be symptoms of lung infection:

- Fever or chills
- Increased mucus production, change in mucus colour
- Increased cough or increased breathing difficulties

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 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 medicine 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):

- 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 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 heart beat (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 (although this effect occurs mainly in children).
- Disturbed sleep.

- Allergic skin rash.

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

- **Breathing difficulties or wheezing that gets worse straight after taking Sametec Airmaster.** If this happens **stop using your Sametec Airmaster inhaler.** Use your fast acting 'reliever' inhaler to help your breathing **and tell your doctor straight away.**
- Sametec Airmaster 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 this combination of medicines to control your asthma.
- Behavioural changes, such as being unusually active and irritable (although these effects occur mainly in children).
- Uneven or irregular heart beat or an extra heart beat (arrhythmias). Tell your doctor, but do not stop taking Sametec Airmaster unless the doctor tells you to stop.
- A 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 are more likely to occur in children).
- 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 national reporting system:

HPRA Pharmacovigilance.

Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Sametec Airmaster

- **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 carton and the label of your inhaler after EXP. The expiry date refers to the last day of that month.
- Do not store above 30 °C.
-
- 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 Sametec Airmaster contains

- The active substances are salmeterol and fluticasone propionate.

Sametec Airmaster 50 microgram /100 microgram

Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 47 micrograms of salmeterol (as salmeterol xinafoate) and 92 micrograms of fluticasone propionate. This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as salmeterol xinafoate) and 100 micrograms fluticasone propionate.

Sametec Airmaster 50 microgram /250 microgram

Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 45 micrograms of salmeterol (as salmeterol xinafoate) and 229 micrograms of fluticasone

propionate. This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as salmeterol xinafoate) and 250 fluticasone propionate.

Sametec Airmaster 50 microgram /500 microgram

Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 43 micrograms of salmeterol (as salmeterol xinafoate) and 432 micrograms of fluticasone propionate. This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as salmeterol xinafoate) and 500 fluticasone propionate.

- The other ingredient is lactose monohydrate (see section 2 under ‘Sametec Airmaster contains lactose’) (which contains milk proteins).

What Sametec Airmaster looks like and contents of the pack

- The Sametec Airmaster contains a foil strip of blisters filled with white to off white powder. The foil protects the powder for inhalation from the effects of the atmosphere.
- Each dose is pre-dispensed.
- The white plastic devices with light pink (for 50/100 microgram strength), pink (for 50/250 microgram strength) or mauve (for 50/500 microgram strength) mouthpiece cover are packed in cartons which hold:
1, 2, 3 or 10 × inhaler(s) each containing 60 inhalations.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Oy Medfiles Ltd, Volttikatu 5, Volttikatu 8, Kuopio, 70700, Finland

Adamed Pharma S.A., ul. Marszałka Józefa Piłsudskiego 5, 95-200 Pabianice, Poland

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

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

Austria	Salmeterol/Fluticasone STADA 50 Mikrogramm /100 Mikrogramm einzeldosiertes Pulver zur Inhalation Salmeterol/Fluticasone STADA 50 Mikrogramm /250 Mikrogramm einzeldosiertes Pulver zur Inhalation Salmeterol/Fluticasone STADA 50 Mikrogramm /500 Mikrogramm einzeldosiertes Pulver zur Inhalation
France	PROPIONATE DE FLUTICASONE/SALMETEROL EG 100 microgrammes/50 microgrammes/dose, poudre pour inhalation en récipient unidose PROPIONATE DE FLUTICASONE/SALMETEROL EG 250 microgrammes/50 microgrammes/dose, poudre pour inhalation en récipient unidose PROPIONATE DE FLUTICASONE/SALMETEROL EG 500 microgrammes/50 microgrammes/dose, poudre pour inhalation en récipient unidose
Germany	Salmeterol/Fluticasonepropionat AL 50 Mikrogramm/100 Mikrogramm einzeldosiertes Pulver zur Inhalation Salmeterol/Fluticasonepropionat AL 50 Mikrogramm/250 Mikrogramm einzeldosiertes Pulver zur Inhalation

Salmeterol/Fluticasonpropionat AL 50 Mikrogramm/500 Mikrogramm
einzeldosiertes Pulver zur Inhalation

Ireland	Sametec Airmaster
Italy	SALMETEROLO E FLUTICASONE EG STADA
Poland	DUEXON PRO
Portugal	Inhalok [®] Airmaster [®] 50 microgramas/100 microgramas/dose pó para inalação, em recipiente unidose Inhalok [®] Airmaster [®] 50 microgramas/250 microgramas/dose pó para inalação, em recipiente unidose Inhalok [®] Airmaster [®] 50 microgramas/500 microgramas/dose pó para inalação, em recipiente unidose
Spain	Inhalok [®] Airmaster [®] 50 microgramas/250 microgramas/inhalación, polvo para inhalación (unidosis) Inhalok [®] Airmaster [®] 50 microgramas/500 microgramas/inhalación, polvo para inhalación (unidosis)
Sweden	Sipova Airmaster
United Kingdom	Fixkoh Airmaster

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