Package leaflet: Information for the patient

Avenor 25 microgram /50 microgram per metered dose pressurized inhalation, suspension.
Avenor 25 microgram /125 microgram per metered dose pressurized inhalation, suspension.
Avenor 25 microgram /250 microgram per metered dose pressurized inhalation, suspension.

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

1. What Avenor is and what it is used for

Avenor contains two active substances, salmeterol (as xinafoate) 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.

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

You must use Avenor every day as directed by your doctor. This will make sure that it works properly in controlling your asthma.

Avenor helps to stop breathlessness and wheeziness coming on. However Avenor 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 'reliever' inhaler with you.

2. What you need to know before you use Avenor

Do not use Avenor:
- If you are allergic (hypersensitive) to salmeterol, fluticasone propionate or to the other ingredient norflurane (HFA 134a).

Warnings and precautions

Talk to your doctor or pharmacist before using Avenor. Your doctor will supervise your treatment more closely if you have medical conditions such as:
- Heart disease, including an irregular or fast heart beat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (Avenor 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.

If you have ever had any of these conditions, tell your doctor before you use Avenor.

Other medicines and Avenor
- Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and medicines for asthma.
- Some medicines may increase the effects of Avenor and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Tell your doctor if you are taking the following medicines, before starting to use Avenor:
- ß blockers (such as atenolol, propranolol and sotalol). ß blockers are mostly used for high blood pressure or other heart conditions.
- Medicines to treat infections (such as ritonavir, 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 Avenor, including irregular heartbeats, or may make side effects worse.
- 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

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

3. How to use Avenor

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 Avenor 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 Avenor or reduce the dose of Avenor without talking to your doctor first.
- Avenor should be inhaled through the mouth into the lungs.
- Use your Avenor always taking the count of the actuations.
- The inhaler has been designed to deliver 120 actuations. However it is not possible to tell when the inhaler is empty and when the 120 puffs have been released. There may still be a small amount of fluid left over in the container. Please make sure that your inhaler is replaced after you have released 120 puffs so that you can be certain that you are getting the right amount of your medicine in each puff.

Adults and adolescents aged 12 years and over
- Avenor 25/50 - 2 puffs twice a day
- Avenor 25/125 - 2 puffs twice a day
- Avenor 25/250 - 2 puffs twice a day

Children 4 to 12 years of age
- Avenor 25/50 - 2 puffs twice a day
- Avenor is not recommended for use in children below 4 years of age

Your symptoms may become well controlled using Avenor 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.

When you are using Avenor for asthma, your doctor will want to regularly check your symptoms.

However, 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 Avenor 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.

Instructions for use
- Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using Avenor properly or as prescribed may mean that it will not help your asthma as it should.
- The medicine is contained in a pressurized canister in a plastic casing with a mouthpiece.
- A new full inhaler has enough medicine for a minimum of 120 actuations of medication. After 120 puffs the inhaler may no longer have enough medicine to give a full dose of medication.

Testing your inhaler
1. Before using the inhaler for the first time, test that it is working. To test the inhaler remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.
2. To make sure the inhaler works, give it a good shake, then point the mouthpiece away from you and press the canister firmly to release a puff into the air. Repeat these steps, shaking the inhaler before releasing a second puff into the air. The total puffs released into the air, before using the inhaler, should be two.
3. After these first two test puffs, you can start using your inhaler.
4. If you have not used your inhaler for a week or more than test the inhaler. To test the inhaler give it a good shake, then point the mouthpiece away from you and press the canister firmly to release two puffs into the air.

Warnings

Never detach the metal canister from the inhaler at any time.

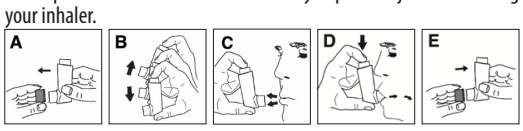
If the inhaler gets very cold (below 0 °C), take the metal canister out of the plastic case and warm it in your hands for few minutes before use. Never use anything else to warm it up. After warming and before using, press the canister firmly to release two puffs into the air.

Re-ordering

Before your inhaler runs out of medicine you must re-order a new inhaler, so that you are not left without medication.

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 (Figure A).
3. Check inside and outside to make sure that the mouthpiece is clean and free of dust or other loose particles.
4. Shake the inhaler 4 or 5 times to ensure that the contents of the inhaler are evenly mixed (Figure B).
5. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable (Figure C).
6. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.
7. 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).
8. 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.
9. Wait about half a minute between taking each puff of medicine and then repeat steps 4 to 8
10. 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.
11. After use always replace the mouthpiece cover straight away to keep out dust (Figure E). When the mouthpiece cover is fitted correctly it will 'click' into position. Do not use too much force.

Do not rush steps 5, 6, 7 and 8. 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 4.

As with all inhalers, caregivers should ensure that children prescribed Avenor use the correct inhalation technique, as described above.

If you or your child find it difficult to use the inhaler, either your doctor or other healthcare provider may recommend using an AeroChamber Plus® spacer device with your inhaler. Your doctor, nurse, pharmacist or other healthcare provider should show you how to use the spacer with your inhaler and how to care for your spacer 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 the spacer without talking to your doctor or nurse first. **Other spacer devices are not recommended for use with Avenor and you should not switch from the AeroChamber Plus® device to another.** It is also important that you do not change or stop using the spacer without talking to your doctor, he will know how to modify the therapy. 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.

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.
- Do not use too much force.
- Do not wash or put any parts of your inhaler in water.

If you use more Avenor 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 Avenor may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use Avenor
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 Avenor
It is very important that you take your Avenor every day as directed.
Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of Avenor. This could make your breathing worse.
In addition, if you suddenly stop taking Avenor or reduce your dose of Avenor 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, nurse 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 Avenor to control your asthma.
Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Avenor. 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 Avenor, stop using Avenor and tell your doctor straight away**. Allergic reactions to Avenor are uncommon (they affect less than 1 person in 100).
Other side effects are listed below:

Very Common (may affects 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 affects 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.
- Throat irritation. Rinsing your mouth out with water and spitting it out immediately after taking each puff may help.
- 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 affects 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 affects up to 1 in 1000 people)
- **Breathing difficulties or wheezing that get worse straight after taking Avenor.** If this happens **stop using your Avenor inhaler**. Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away**.
- Avenor 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 Avenor 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 Avenor unless the doctor tells you to stop.
- A fungal infection in the oesophagus (gullet), which might cause difficulties in swallowing.

Not known, (frequency cannot be estimated from the available data):
- 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 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 Avenor
- **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.
- Do not store above 25°C.
- Straight after use, replace the mouthpiece cover firmly and click it into position. Do not use excessive force.
- The canister contains a pressurized liquid. Do not expose to temperatures higher than 50°C, protect from direct sunlight. Do not pierce, break or burn the canister even when apparently empty.
- As with most inhaled medicinal products in pressurized canisters, the therapeutic effect of this medicinal product may decrease when the canister 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 Avenor contains
Each metered dose (ex valve) contains 25 micrograms of salmeterol (as salmeterol xinafoate) and 50, 125 or 250 micrograms of fluticasone propionate.
The other ingredient is propellant: norflurane (HFA 134a).
This medicine contains fluorinated greenhouse gases.
Each inhaler of 120 actuation contains 11.2 g of HFA-134a corresponding to 0.016 tonne CO2 equivalent (global warming potential GWP = 1, 430).

What Avenor looks like and contents of the pack
- Avenor is supplied to you in a metered dose inhaler which delivers your medicine in a pressurized suspension for you to inhale through your mouth into your lungs.
- The pressurized canister contains a white homogenous suspension for inhalation.
- The canister is fitted into a plastic casing incorporating a mouthpiece and fitted with a lilac dust cap
  or
  The canister is fitted into a plastic casing incorporating a mouthpiece and fitted with a purple dust cap.
  or
  The canister is fitted into a plastic casing incorporating a mouthpiece and fitted with a violet dust cap.
- Each pack contains 1 inhaler or 3 inhalers. Each inhaler contains 120 actuations.
- Not all pack-sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK
Manufacturer
Genetic S.p.A. Contrada Canfora Fisciano 84084, Salerno Italy
This leaflet was last revised in November 2024.

ZENTIVA 1065044006