

Package leaflet: Information for the user

Salmeterol/Flutikason Devatis 25 microgram/125 microgram/actuation, pressurised inhalation, suspension

Salmeterol/Flutikason Devatis 25 microgram/250 microgram/actuation, pressurised inhalation, suspension

salmeterol / fluticasone propionate

Read all of this leaflet carefully before you start taking 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 {invented name} is and what it is used for
2. What you need to know before you use {invented name}
3. How to use {invented name}
4. Possible side effects
5. How to store {invented name}
6. Contents of the pack and other information

1. What {invented name} is and what it is used for

{Invented name} 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.

{Invented name} is not suitable for children under the age of 12 years. For these patients a different inhaled salmeterol fluticasone product available in lower strength (25/50 microgram) should be used.

The doctor has prescribed this medicine to help prevent breathing problems such as asthma. You must use {invented name} every day as directed by your doctor. This will make sure that it works properly in controlling your asthma.

{Invented name} helps to stop breathlessness and wheeziness coming on. However {invented name} 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 ‘rescue’ inhaler with you.

2. What you need to know before you use {invented name}

Do not use {invented name}:

- If you are **allergic** to salmeterol, fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before using {invented name} if you have:

- Heart disease, including an irregular or fast heart beat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus ({invented name} 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.

Children

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

Other medicines and {invented name}

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines for asthma or any medicines obtained without a prescription. This is because {invented name} 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 {invented name}:

- Beta-blockers (such as atenolol, propranolol and sotalol). Beta-blockers are mostly used for high blood pressure or other heart conditions.
- 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 experiencing side effects with {invented name}, including irregular heart beats, or may make side effects worse. Your doctor may wish to monitor you carefully if you are taking these medicines.
- Corticosteroids (by oral use 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 breast-feeding

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.

Driving and using machines

{Invented name} is not likely to affect your ability to drive or use machines.

3. How to use {invented name}

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 {invented name} 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 {invented name} or reduce the dose of {invented name} without talking to your doctor first
- {Invented name} should be inhaled through the mouth into the lungs.

Adults and adolescents aged 12 years and over

- {Invented name} 25/125 microgram: 2 puffs twice a day
- {Invented name} 25/250 microgram: 2 puffs twice a day

Your symptoms may become well controlled using {invented name} 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.

If you are using {invented name} for asthma, your doctor will want to regularly check your symptoms.

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 {invented name} 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 the {invented name} properly or as prescribed may mean that it will not help your asthma as it should.
- The medicine is contained in a pressurised metal container in a plastic casing with a mouthpiece.
- There is a dose indicator in front of the inhaler which tells you how many doses are left. Each time you press the metal container, a puff of medicine is released and the dose indicator is counting down.
- Take care not to drop the inhaler as this may cause the dose indicator to count down.

Testing your inhaler

1. When using your inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.
2. To make sure that it works, shake it well, point the mouthpiece away from you and press the metal container to release a puff into the air. Repeat these steps until the dose indicator shows the number "120" (4 to 5 puffs). Shake the inhaler immediately before releasing each puff. If you have not used your inhaler for a week or more, remove the mouthpiece cover and shake the inhaler well (4 to 5 times). During the use of the inhaler the dose indicator counts down to zero.



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 (as described in step 1 of Testing your inhaler). Check inside and outside to make sure that the mouthpiece is clean and free of loose objects.
3. Shake the inhaler well (4 to 5 times) to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.
4. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable.
5. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.
6. Breathe in through your mouth slowly and deeply. Just after starting to breathe in, press firmly down on the top of the metal container to release a puff of medicine. Do this while still breathing in steadily and deeply.
7. 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.
8. Wait about half a minute between taking each puff of medicine and then repeat steps 3 to 7.
9. 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.
10. After use always replace the mouthpiece cover straight away to keep out dust. When the mouthpiece cover is fitted correctly it will 'click' into position. Do not use too much force.

Do not rush steps 4, 5, 6 and 7. 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 3.



As with all inhalers, caregivers should ensure that children prescribed {invented name} use 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 a spacer device such as the AeroChamber Plus® with your inhaler. Your doctor, nurse, pharmacist or other healthcare provider should show you how to use the spacer device with your inhaler and how to care for your spacer device 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 it without talking to your doctor or nurse first.

It is recommended to use the AeroChamber Plus® spacer device with {invented name} as data has shown adequate compatibility. Continue to use the same make of spacer device as switching between spacer devices can result in changes in the dose delivered to the lungs. Always talk to your doctor before making any changes to your asthma treatment.

Older children or 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.

When the dose indicator approaches 40 remaining doses, the background colour starts changing from green to red. You should get a replacement when the dose indicator shows the number “20”. Stop using the inhaler when the dose indicator shows “0” as any puffs left in the device may not be enough to give you a full dose. Never try to alter the numbers on the dose indicator or detach the counter from the metal container.

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 container 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 put the metal container in water.

If you use more {invented name} 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 {invented name} may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use {invented name}

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 {invented name}

It is very important that you take your {invented name} every day as directed. **Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of {invented name}.** This could make your breathing worse.

In addition, if you suddenly stop taking {invented name} or reduce your dose of {invented name} 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 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 {invented name} to control your asthma.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using {invented name}. 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 {invented name}, stop using {invented name} and tell your doctor straight away.** Allergic reactions to {invented name} are uncommon (they affect less than 1 person in 100).

Other side effects are listed below:

Very common (affects more than 1 person in 10)

- Headache - this usually gets better as treatment continues.
- Increased number of colds have been reported in patients with COPD.

Common (affects less than 1 person in 10)

- 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.
- 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 (affects less than 1 person in 100)

- 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 (affects less than 1 person in 1000)

- **Breathing difficulties or wheezing that get worse straight after taking {invented name}.** If this happens **stop using your {invented name} inhaler.** Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away.**
- {Invented name} 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 {invented name} 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 {invented name} unless the doctor tells you to stop.
- 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 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 [the national reporting system](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store {invented name}

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.

This medicinal product does not require any special storage conditions.

The metal container contains a pressurised liquid. Do not expose to temperatures higher than 50°C, protect from direct sunlight. Do not pierce or burn the metal container even when empty.

As with most inhaled medicinal products in pressurised metal containers, the therapeutic effect of this medicinal product may decrease when the metal container 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 {invented name} contains

- The active substances are salmeterol (as salmeterol xinafoate) and fluticasone propionate
Each actuation contains 25 micrograms of salmeterol (as xinafoate) and 125 or 250 micrograms of fluticasone propionate.
- This medicine contains fluorinated greenhouse gases.
Each inhaler contains 10.54 g HFA-134a corresponding to 0.0151 tonne CO₂ equivalent (global warming potential GWP = 1430).

What {invented name} looks like and contents of the pack

- {Invented name} is supplied to you in a metered dose inhaler which delivers your medicine in a pressurised suspension for you to inhale through your mouth into your lungs.
- One pressurised metal container delivers 120 actuations.
- The pressurised metal container contains a white to off white suspension for inhalation.
- The metal containers are fitted into a plastic casing incorporating a mouthpiece and fitted with dust caps.
- The inhalers are available in cartons which hold 1, 2, 3 or 10 inhalers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

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

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

<[To be completed nationally]>

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