

PACKAGE LEAFLET

Package leaflet: Information for the user

Gardette 160 micrograms /4.5 micrograms/actuation pressurised inhalation, suspension Budesonide/Formoterol fumarate dihydrate

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

1. What Gardette is and what it is used for

Gardette is an inhaler that is used to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) in adults aged 18 and older. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking. Gardette contains two different medicines: budesonide and formoterol fumarate dihydrate.

- Budesonide belongs to a group of medicines called ‘corticosteroids’. It works by reducing and preventing swelling and inflammation in your lungs.
- Formoterol fumarate dihydrate belongs to a group of medicines called ‘long-acting beta₂ adrenoceptor agonists’ or ‘bronchodilators’. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

Do not use this medicine as a “reliever” inhaler.

2. What you need to know before you use Gardette

Do not use Gardette:

- if you are allergic to budesonide, formoterol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Gardette if:

- You are diabetic.
- You have a lung infection.
- You have high blood pressure or you have ever had a heart problem (including an uneven heart beat, a very fast pulse, narrowing of the arteries or heart failure).
- You have problems with your thyroid or adrenal glands.
- You have low levels of potassium in your blood.
- You have severe liver problems.

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

Children and adolescents

Gardette is not recommended for children and adolescents under 18 years.

Other medicines and Gardette

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Beta-blocker medicines (such as atenolol or propranolol for high blood pressure), including eyedrops (such as timolol for glaucoma).
- Medicines for a fast or uneven heart beat (such as quinidine).
- Medicines like digoxin, often used to treat heart failure.
- Diuretics, also known as 'water tablets' (such as furosemide). These are used to treat high blood pressure.
- Steroid medicines that you take by mouth (such as prednisolone).
- Xanthine medicines (such as theophylline or aminophylline). These are often used to treat COPD or asthma.
- Other bronchodilators (such as salbutamol).
- Tricyclic anti-depressants (such as amitriptyline) and the anti-depressant nefazodone.
- Phenothiazine medicines (such as chlorpromazine and prochlorperazine).
- Medicines called 'HIV-protease inhibitors' (such as ritonavir) to treat HIV infection.
- Medicines to treat infections (such as ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin and telithromycin).
- Medicines for Parkinson's disease (such as leva-dopa).
- Medicines for thyroid problems (such as levo-thyroxine).

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using Gardette.

Also tell your doctor or pharmacist if you are going to have a general anaesthetic for an operation or for dental work.

Pregnancy, breast-feeding and fertility

- If you are pregnant, or planning to get pregnant, talk to your doctor before using Gardette - do not use Gardette unless your doctor tells you to.
- If you get pregnant while using Gardette, do not stop using Gardette but talk to your doctor immediately.
- If you are breast-feeding, talk to your doctor before using Gardette.

Driving and using machines

Gardette has no or negligible effect on your ability to drive or to use tools or machines.

3. How to use Gardette

- Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- It is important to use Gardette every day, even if you have no COPD symptoms at the time.

The usual dose is 2 inhalations twice a day. Gardette is not recommended for children or adolescents under 18 years of age.

If you have been taking steroid tablets for your COPD, your doctor may reduce the number of tablets that you take, once you start to use Gardette. If you have been taking oral steroid tablets for a long time, your doctor may want you to have blood tests from time to time. When reducing oral steroid

tablets, you may feel generally unwell even though your chest symptoms may be improving. You might experience symptoms such as a stuffy or runny nose, weakness or joint or muscle pain and rash (eczema). If any of these symptoms bother you, or if symptoms such as headache, tiredness, nausea (feeling sick) or vomiting (being sick) occur, please contact your doctor immediately. You may need to take other medication if you develop allergic or arthritic symptoms. You should speak to your doctor if you are concerned as to whether you should continue to use Gardette.

Your doctor may consider adding steroid tablets to your usual treatment during periods of stress (for example, when you have a chest infection or before an operation).

Important information about your COPD symptoms

If you feel you are getting breathless or wheezy while using Gardette, you should continue to use Gardette but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- Your breathing is getting worse or you often wake up at night feeling breathless.
- Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.
- These signs could mean that your COPD is not being properly controlled and you may need different or additional treatment immediately.

Your doctor may also prescribe other bronchodilator drugs, for example anticholinergics (such as tiotropium or ipratropium bromide) for your COPD disease.

Information about your Gardette

- Before starting to use your Gardette, remove it from the foil wrapper. Throw away the wrapper as well as the drying agent which is inside the wrapper. If the drying agent has leaked out of its packet, do not use the inhaler.
- After you have taken the inhaler out of its foil wrapper, you should use it within 3 months. Write the use by date (3 months from opening the wrapper) on the inhaler label to remind you when to stop using the inhaler.
- The parts of your inhaler are shown in the picture. The inhaler will already be assembled when you first receive it. Do not take it apart. If the canister becomes loose, put it back in the inhaler and keep using the inhaler.



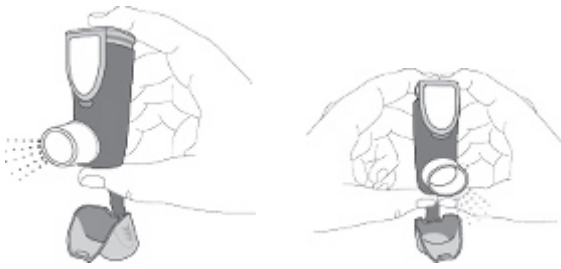
Preparing your Gardette

You need to prepare your inhaler for use in the following situations:

- If you are using your new Gardette for the first time.
- If you have not used it for more than 7 days.
- If it has been dropped.

To prepare your inhaler for use, follow the instructions below:

1. Shake the inhaler well for at least 5 seconds to mix the contents of the aerosol canister.
2. Remove the mouthpiece cover by pressing lightly on the bumps on the side. The strap on the mouthpiece cover will stay attached to the inhaler.
3. Hold the inhaler upright. Then press the counter (on the top of the inhaler) to release a puff into the air. You can use one or both hands, as shown in the pictures.



4. Release your finger(s) from the counter.
5. Wait for 10 seconds, shake well and then repeat steps 3 and 4.
6. Your inhaler is now ready for use.

How to take an inhalation

Each time you need to take an inhalation, follow the instructions below:

1. Shake the inhaler well for at least 5 seconds to mix the contents of the aerosol canister.
2. Remove the mouthpiece cover by pressing lightly on the bumps on the side. Check that the mouthpiece is not blocked.
3. Hold your inhaler upright (using one or both hands). Breathe out gently.
4. Place the mouthpiece gently between your teeth. Close your lips.
5. Start to breathe in slowly and deeply through your mouth. Press the counter (on the top of the inhaler) firmly to release a puff. Keep breathing in for a short while after pressing the counter. Breathing in at the same time as pressing the counter ensures that the medicine reaches your lungs.
6. Hold your breath for 10 seconds, or for as long as it is comfortable.
7. Before you breathe out, release your finger from the counter and remove the inhaler from your mouth. Keep the inhaler upright.
8. Then breathe out slowly. To take another inhalation, shake the inhaler well for at least 5 seconds and repeat steps 3 to 7.
9. Replace the mouthpiece cover.
10. Rinse your mouth with water after your daily morning and evening doses and spit it out.



Using a spacer device

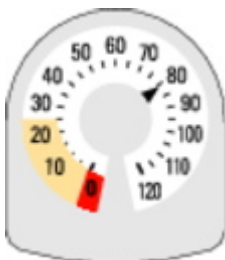
Your doctor, nurse or pharmacist may suggest that you use a spacer device (e.g. **AeroChamber Plus Flow Vu** or **AeroChamber Plus**). Follow the instructions in the leaflet that is packed with the spacer device.

Cleaning your Gardette

- Wipe the inside and outside of the mouthpiece at least once a week with a dry tissue.
- Do not use water or liquids and do not remove the canister from the inhaler.

How will I know when to replace my Gardette?

- The counter on the top of your inhaler tells you how many puffs (actuations) are left in your Gardette. It starts with 120 puffs when it is full.



- Each time you take an inhalation, or release a puff into the air, the arrow counts down towards zero ('0').
- When the arrow first enters the yellow area, this means that there are about 20 puffs left.



- When the arrow reaches '0', you must stop using your new Gardette. Your inhaler may not feel empty and it may seem as though it still works. However, you will not get the right amount of medicine if you keep using it.

If you use more Gardette than you should

If you use more Gardette than you should, contact your doctor or pharmacist for advice. The following effects may happen: trembling, headache or a rapid heartbeat.

If you forget to use Gardette

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do **not** take a double dose to make up for a forgotten dose.

If you stop using Gardette

Before you stop using Gardette, you should talk to your doctor or your pharmacist. If you stop using Gardette the signs and symptoms of COPD may worsen.

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.

If either of the following happens to you, stop using Gardette straightaway and talk to your doctor immediately:

- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty to swallow) rash or hives together with difficulties to breathe (angioedema) and/or sudden feeling of faintness. This may mean that you are having an allergic reaction. This happens rarely, affecting less than 1 in 1,000 people.
- Sudden acute wheezing or shortness of breath immediately after using your inhaler. If either of these symptoms occurs, stop using your Gardette straightaway and use your 'reliever' inhaler. Contact your doctor immediately as you may need to have your treatment changed. This happens very rarely, affecting less than 1 in 10,000 people.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use Gardette.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your Gardette.
- Mild sore throat, coughing and a hoarse voice.

- Headache.
- Pneumonia (infection of the lung) in COPD patients.

Tell your doctor if you have any of the following while taking Gardette, they could be symptoms of a lung infection:

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

Uncommon (may affect up to 1 in 100 people)

- Feeling restless, nervous or agitated.
- Disturbed sleep.
- Feeling dizzy.
- Nausea (feeling sick).
- Fast heart beat.
- Bruising of the skin.
- Muscle cramps.
- Blurred vision.

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

- Rash, itching.
- Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing comes on suddenly after using Gardette stop using Gardette and talk to your doctor immediately.
- Low levels of potassium in your blood.
- Uneven heart beat.

Very rare (may affect up to 1 in 10,000 people)

- Depression.
- Changes in behaviour, especially in children.
- Chest pain or tightness in the chest (angina pectoris).
- An increase in the amount of sugar (glucose) in your blood.
- Taste changes, such as an unpleasant taste in the mouth.
- Changes in your blood pressure.

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:

- changes in bone mineral density (thinning of the bones)
- cataract (clouding of the lens in the eye)
- glaucoma (increased pressure in the eye)
- a slowing of the rate of growth of children and adolescents.
- an effect on the adrenal gland (a small gland next to the kidney).

These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

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 listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gardette

- 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, carton and foil wrapper after EXP. The expiry date refers to the last day of that month.
- As with most inhaled medicines in pressurised canisters, the effect of this medicine may decrease when the canister is cold. For best results, this medicine should be at room temperature before use. Do not refrigerate or freeze. Protect from frost and direct sunlight.
- After you have taken the inhaler out of its foil wrapper, you should use it within 3 months. Write the use by date (3 months from opening the wrapper) on the inhaler label to remind you when to stop using the inhaler.
- Always replace the mouthpiece cover firmly and snap into position after using your inhaler.
- 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.

Warning: The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister. The canister should not be broken, punctured or burnt, even when it seems empty.

6. Contents of the pack and other information

What Gardette contains

The active substances are budesonide and formoterol fumarate dihydrate. Each puff (actuation) contains 160 micrograms of budesonide and 4.5 micrograms of formoterol fumarate dihydrate.

The other ingredients are apaflurane (HFA 227), povidone and macrogol. This is a CFC-free inhaler.

This medicine contains fluorinated greenhouse gases. Each inhaler contains 10.6 g of apaflurane (HFC-227ea) corresponding to 0.034 tonne CO₂ equivalent (global warming potential GWP = 3,220).

What Gardette looks like and contents of the pack

Gardette is an inhaler containing your medicine. The pressurised canister, with attached dose indicator, contains a white suspension for inhalation. The canister is fitted into a red plastic actuator with a white plastic mouthpiece and an integrated grey plastic dust cap. Each inhaler contains 120 puffs (actuations) after it has been prepared for use. Each inhaler is individually packed in a foil wrapper containing a drying agent.

Gardette, 160 micrograms/4.5 micrograms/actuation pressurised inhalation, suspension (Budesonide/Formoterol fumarate dihydrate) is available in packs of one inhaler.

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:

Country	Trade name and strength
Spain	Rilast 160 microgramos /4,5 microgramos/inhalación suspensión para inhalación en envase a presión
Sweden	Gardette 160 mikrogram /4.5 mikrogram/inhalation

This leaflet was last revised in MM/YYYY

2024-11-22[To be completed nationally]