

Meterol Inhaler

Consumer Medicine Information

Salmeterol (as xinafoate)

25 mcg suspension for inhalation

120 ACTUATIONS

What is in this leaflet

The information enclosed answers several general questions about your Meterol Inhaler. This leaflet does not include all the accessible information on Meterol Inhaler. All medication has benefits and risks. Your doctor will have considered the risks of you using Meterol Inhaler against the benefits expected. Discuss with your doctor or pharmacist any concerns you may have.

This leaflet was last updated on the date at the end of this leaflet.

Keep this information with the medicine and refer to this leaflet if you have any queries.

Meterol Inhaler is one component of your asthma plan to help control and manage your condition. Your asthma plan should be checked by your doctor on a regular basis. Discuss any concerns about your plan with your doctor.

What your Meterol Inhaler is used for

Meterol Inhaler contains salmeterol (as xinafoate), a bronchodilator which opens the airways in your lungs.

Each Meterol Inhaler delivers 25 mcg of salmeterol (as xinafoate) per actuation (or dose). Your Meterol Inhaler contains 120 actuations.

This inhaler may have a body or cap colour that is different to your previous inhaler. This does not affect the way it works.

Each Meterol Inhaler also contains the propellant HFA-134a, less than 0.002g ethanol, and less than 0.00001mg soy lecithin per actuation.

Meterol Inhaler does not contain any chlorofluorocarbon (CFC) propellants. It does contain a non-CFC propellant, known as HFA-134a. If you have previously used another inhaler, you might notice that the spray from Meterol Inhaler tastes or feels different in your mouth, or that the inhaler sounds different when sprayed. This does not affect the way your inhaler works.

Meterol Inhaler used each morning and evening will help you breathe easier and help prevent asthma attacks. This also includes asthma that you get at night or brought on by exercise. If you are being treated for asthma, you should use a

“preventer” medicine regularly, such as an inhaled corticosteroid with your Meterol Inhaler.

If you have COPD, taking Meterol Inhaler each morning and evening will help prevent breathing problems. Your doctor will inform you of other medication that you may be required to take for COPD.

Meterol Inhaler helps prevent breathlessness and wheezing. It does not work once you are breathless or wheezy.

Make sure you always carry your “reliever” inhaler (e.g. Salbutamol) with you. In the event of an asthma attack, use your “reliever” inhaler, NOT Meterol Inhaler.

Before you use your Meterol Inhaler

If you have any concerns about using your Meterol Inhaler, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Do not give it to anyone else even if their symptoms are the same as yours, as it may harm them.

Tell your doctor before using Meterol Inhaler if you:

- Are allergic to salmeterol or the other ingredients in your inhaler;
- Have had to discontinue Meterol Inhaler in the past or other medications for asthma;
- Are pregnant or intending to become pregnant ;
- Are breastfeeding;
- Have a thyroid condition;
- Have a heart condition;
- Have diabetes;
- Are taking ANY other medicines.

Using other medicines

Please tell your doctor, pharmacist or asthma nurse if you are taking or have recently taken any other medicines, including asthma medicines and any inhalers, and including medicines obtained without a prescription. This is because Meterol Inhaler may not be suitable to be taken with other medicines.

- Please inform your doctor or asthma nurse before using Meterol Inhaler if you are currently being treated for any fungal infections with medicines containing ketoconazole or itraconazole, or if you are being treated for HIV with ritonavir. These medicines may increase the risk of you experiencing side effects with salmeterol, including irregular heartbeats, or may make side effects worse.
- Beta blockers should be avoided when using Meterol Inhaler, unless your doctor tells you to take them. Beta blockers, including atenolol, propranolol and sotalol, are mostly used for the treatment of high blood pressure or other heart conditions.

Please tell your doctor or asthma nurse if you are taking β blockers or have recently been prescribed β blockers as they may reduce or abolish the effects of salmeterol.

- Salmeterol can reduce the amount of potassium in your blood. If this happens, you may notice an uneven heartbeat, muscle weakness or cramp. This is more likely to happen if you use salmeterol with some medicines used to treat high blood pressure (diuretics) and other medicines used to treat breathing problems such as theophylline or steroids. Your doctor may ask you to have blood tests to check the amount of potassium in your blood from time to time.
- Salmeterol should be used with extreme caution with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such medicines, because the action of salmeterol on the vascular system may be potentiated by these agents.

If you have any concerns discuss them with your doctor or asthma nurse.

Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant, planning to get pregnant or breast-feeding, you should talk to your doctor or asthma nurse before starting to use Meterol Inhaler. They will assess if you can use Meterol Inhaler during this time.

Driving and using machines

The possible side effects associated with Meterol Inhaler are unlikely to affect your ability to drive or use machines.

Using your Meterol Inhaler

Always use Meterol Inhaler exactly as your doctor or asthma nurse has told you. The dispensing label should tell you how much to take and how often.

Meterol Inhaler should not be used to remedy any conditions other than what your doctor has prescribed it for.

If you find it difficult to use your inhaler and breathe in at the same time, you may find a spacer device helpful. Ask your doctor or pharmacist about this.

Meterol Inhaler is for oral inhalation only.

The usual doses of Meterol Inhaler are:

Adults and adolescents aged 12 years and over

The usual starting dose for asthma (and COPD in adults) is two doses (2 x 25mcg) twice a day. If you have more severe asthma, the doctor may tell you to take four doses (4 x 25mcg) twice a day.

Children aged 4 to 11 years

The usual dose for asthma is two doses (2 x 25mcg) twice a day.

To get the full benefit from your Meterol Inhaler, you should take it regularly in the morning and evening. Do not use your Meterol Inhaler more than prescribed or take more doses than the medical advice received.

Children aged less than 4 years

Meterol Inhaler is not recommended in children under 4 years of age due to insufficient clinical data.

While you are using your Meterol Inhaler

In the event of an asthma attack, use your “reliever” inhaler (e.g. Salbutamol), NOT your Meterol Inhaler.

Contact your doctor immediately if

- Your breathing suddenly becomes more difficult just after you have used your Meterol Inhaler;
- The effects of your Meterol Inhaler does not continue as long as normal or does not assist your breathing the same as usual;
- Your asthma symptoms do not get better, or get worse, after seven days of using Meterol Inhaler.

If you start taking any other medicine while you are using Meterol Inhaler, tell your doctor or pharmacist.

Do not change the dosage or stop using your Meterol Inhaler under any circumstances unless you have approval from your doctor.

If you forget to use your Meterol Inhaler

If you have forgotten to take your normal dose at the correct time, take your next dose as soon as you remember. However, if you forget to take your Meterol Inhaler close to the time of the next dose then simply miss out the dose you have forgotten.

Do not take a double dose of Meterol Inhaler at any given time if you have missed a dose.

If you have difficulty remembering when the next dose of your inhaler is due, talk to your pharmacist for advice.

If you experience tightness in your chest or you become wheezy before you are due for the next dose, use your reliever inhaler (e.g. Salbutamol) as normal.

If you use too much of your Meterol Inhaler (overdose)

If you or someone else takes too much of your Meterol Inhaler, immediately phone the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or your doctor, even if you do not feel unwell or there are no signs of overdose symptoms.

Side effects

If you experience any of the following side effects, stop taking Meterol Inhaler and seek immediate medical attention as you may be allergic to the medicine:

- Itching, rash or reddened skin;
- Swelling of the eye lids, lips, face or throat;
- Low blood pressure causing you to feel weak or dizzy;
- Collapse;
- Increase in wheezing and shortness of breath immediately after using your inhaler.

If you experience any of the below side effects advise your nurse, pharmacist or doctor but do not discontinue using your Meterol Inhaler.

Other side effects are:

- Muscle cramps;
- Feeling shaky, fast or irregular heartbeat (palpitations), headache, shaking hands (tremor). Tremors are more likely to occur if you are taking more than two puffs twice daily. These side effects do not last long and occur less as treatment with salmeterol continues;
- Rash;
- Very fast heart rate (tachycardia);
- Feeling nervous;
- Dizziness;
- Difficulty in sleeping (insomnia);
- A fall in the amount of potassium in the blood (you may notice an irregular heartbeat, muscle weakness and/or muscle cramps);
- An increase in the amount of sugar (glucose) in your blood; (hyperglycaemia). If you have diabetes your doctor may want to monitor your blood sugar more frequently than usual and may need to adjust the treatment you take for your diabetes;
- Sore mouth or throat;
- Feeling sick (nausea);
- Aching, swollen joints;
- Chest pain.

Meterol Inhaler contains medication that is not addictive.

After using your Meterol Inhaler

Storage and disposal

Keep out of reach of children by storing your Meterol Inhaler in a locked cabinet at a height that is hard to reach for children.

Store Meterol Inhaler below 25°C.

The shelf life of Meterol Inhaler is 24 months.

Do not use after the expiry date. The expiry date can be found on the label on the canister and on the bottom of the carton.

When the Meterol Inhaler is not in use, the plastic dust cap should be securely placed back on the mouthpiece of the actuator.

Avoid direct sunlight or heat. Do not store your Meterol Inhaler in your car on a hot day or on a window sill. Protect your Meterol Inhaler from frost.

As with other medication inhaled from aerosol canisters, the effect of the medication may be reduced if the canister is very cold. If this is the case, warm the inhaler in your hands for a few minutes before use. Do not use anything else to assist with warming up the inhaler.

Disposal

If your doctor advises you to stop taking your Meterol Inhaler, or it has exceeded its expiry date, request information from your pharmacist on what to do with any product that is left over.

As the canister is pressurised, no attempt should be made to puncture, or dispose of it by burning.

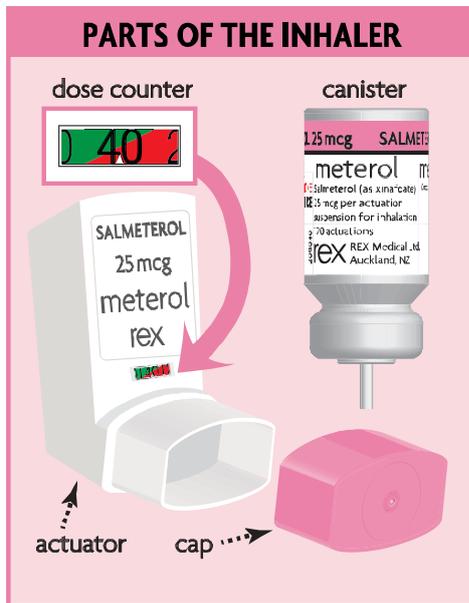
Product Description

What it looks like

Your Meterol Inhaler contains a white plastic actuator that holds a metal canister with a white and pink label. The canister is filled with your medication. The white plastic actuator has the name of your medication embossed on the front along with the name of the molecule of your medication and the strength you have been prescribed. The plastic dust cap is pink.

Instructions for Use

Correct operation of the Meterol Inhaler is essential for successful therapy.



Prior to using the Meterol Inhaler for the first time, remove the plastic dust cap from the mouthpiece of the inhaler, shake inhaler well and depress the canister twice into the air to prime the inhaler.



If the inhaler has not been used for more than one week, remove the plastic dust cap from the mouthpiece of the inhaler, shake the inhaler well and depress the canister once into the air to prime the inhaler.



Technique for proper administration of the Meterol Inhaler is described in the following steps:

1. **Remove the plastic dust cap from the mouthpiece of the inhaler and check the mouthpiece is clean.** Shake inhaler well and prime if necessary.
2. **Hold the inhaler, using either one or two fingers on the top of the canister and your thumb on the base.** Breathe out deeply through your mouth. Place the mouthpiece of the actuator in your mouth taking care to not bite it and close your lips over the mouthpiece.



3. **Start breathing in through your mouth.** Then depress the canister to release one dose while continuing to breathe in deeply and steadily.
4. **Remove the inhaler from your mouth and hold your breath for 10 seconds or as long as comfortable.** Breathe out slowly.
5. **If another dose is required, wait for at least one minute with the inhaler in an upright position, and then repeat steps 2 to 4.**
6. **After use, replace the mouthpiece cover, making sure the dust cap is secure.**

IMPORTANT:

Do not rush steps 2, 3 and 4. It is essential that just before depressing the canister that you begin breathing in as slow as possible.

It is useful to complete this exercise using a mirror for the initial few actuations. If you see “mist or vapour” coming from the sides of your mouth or top of the inhaler, start again from step 2.

Make sure that you are operating your Meterol Inhaler correctly with your pharmacist or doctor on a regular basis. Meterol Inhaler may not work as well as it should if the technique you are using is not correct.

Provide feedback to your doctor if you have any concerns or issues when using your Meterol Inhaler. If different directions have been provided by your doctor, please follow these instructions with care.

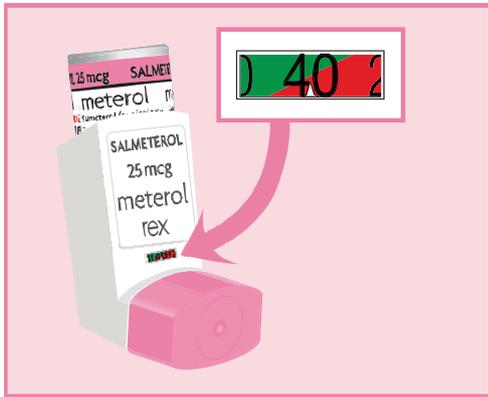
Have a spare Meterol Inhaler available at all times.

Built-in Dose Counter

The Meterol Inhaler has a built-in dose counter to see how many actuations are left in the inhaler.

After Meterol Inhaler is primed for the first time, the dose counter should read 120. This means that there are 120 doses of medicine left in the inhaler. Each time the inhaler is used, the dose counter will count down by one number.

When there are 40 doses of medicine remaining in the Meterol Inhaler, the colour on the dose counter will change from green to red.



When the dose counter on the Meterol Inhaler is red, the patient should ask their doctor for a new inhaler.

The dose counter will stop counting when it reaches 0. This means that there is no medication left in the inhaler and it should be discarded.

The Meterol Inhaler may not feel empty and may continue to operate; however, the right amount of medicine may not be dispensed if the inhaler is continued to be used once the dose counter has reached 0. The dose counter will continue to show 0 even if the inhaler is used again.

The dose counter cannot be reset and is permanently attached to the plastic actuator. Never try to change the numbers on the dose counter.

Cleaning

The Meterol Inhaler plastic actuator should be cleaned at least once a week to ensure that it functions correctly.

NEVER wash or soak any part of the inhaler in water.



Use the following technique to clean your inhaler:

1. Remove the plastic dust cap from the mouthpiece of the inhaler. The metal canister should NOT be removed from the plastic actuator.



2. The plastic mouthpiece and the dust cap are to be wiped inside and outside with a clean dry cloth.
3. Replace the plastic dust cap on to the mouthpiece of the inhaler.

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