GSK logo

Package Leaflet: Information for the User

Ventolin Evohaler
100 micrograms Pressurised Inhalation Suspension
salbutamol (as sulfate)

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, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

What Ventolin Evohaler is and what it is used for

Ventolin Evohaler contains a medicine called salbutamol. This belongs to a group of medicines called fast-acting bronchodilators.
- Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out.
- They help to relieve chest tightness, wheezing and cough.

Ventolin Evohaler is for use in adults, adolescents and children. For babies and children under 4 years of age, see section 3.

Ventolin Evohaler is used to help prevent and treat breathing problems in people with asthma and chronic obstructive airways disease.

What you need to know before you use Ventolin Evohaler

Do not use Ventolin Evohaler:
- if you are allergic to salbutamol sulfate or the other ingredient of this medicine, listed in section 6.

Warnings and precautions
Talk to your doctor, nurse or pharmacist before taking Ventolin Evohaler if:
- you have high blood pressure
- you have an overactive thyroid gland
- you have a history of heart problems such as, severe heart failure, an irregular or fast heartbeat or angina.
- you suffer from acute severe asthma (your doctor may need to carry out blood tests to monitor the amount of potassium in your blood)
- you have diabetes (high blood sugar levels).

Ventolin Evohaler should be used as required rather than regularly.

If your asthma is active (for example you have frequent symptoms or flare ups, such as breathlessness that makes speaking, eating or sleeping difficult, cough, wheezing, tight chest or limited physical ability), you should tell your doctor right away who may start or increase a medicine to control your asthma such as an inhaled corticosteroid.

If your asthma or breathing gets worse tell your doctor straight away. Your chest condition may be getting worse and you could become seriously ill.

If your breathing or wheezing gets worse straight after taking this medicine, **stop using it immediately and tell your doctor as soon as possible.**

Ventolin Evohaler without dose counter
Your inhaler contains enough medicine for 200 puffs only (whether inhaled and/or released into the air for testing) and it contains a propellant gas to deliver the medicine. However, after 200 puffs, your inhaler can continue to spray the gas but without the right dose of salbutamol, so you cannot be sure you will receive any medicine after using 200 puffs. The inhaler does not have a dose counter. Methods of telling that the inhaler is empty like shaking it, weighing it, floating it in water, are not reliable and are not recommended. Cases of severe worsening of asthma symptoms following accidental use of empty inhalers have been reported. You may consider recording the number of puffs used. It is recommended that you have a spare inhaler available. If you are using more than one inhaler, it is recommended to keep track of the number of puffs for each inhaler separately.

Children
An adult should supervise use of the inhaler in children.

Other medicines and Ventolin Evohaler
Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go to hospital.
In particular, tell your doctor, nurse or pharmacist if you are taking:
- medicines for an irregular or fast heartbeat e.g. propranolol
- other medicines for your asthma.
- medicines used to treat high blood pressure e.g. guanethidine and methyldopa
- reserpine (used to treat high blood pressure or severe agitation)
- tricyclic antidepressants
- diuretics, steroids and xanthine derivatives
- anaesthetics such as chloroform, cyclopropane and halothane

Tell your doctor that you are taking Ventolin if you are going to have an operation as it may interact with some anaesthetics.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Ventolin is not likely to affect you being able to drive or use any tools or machines.

How to use Ventolin Evohaler

Always use your Ventolin Evohaler exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Adults and Adolescents (children 12 years and over)

To relieve asthma
One or two puffs (100 or 200 micrograms).

To prevent asthma
Two puffs (200 micrograms) 10-15 minutes before exercise or exposure to a recognised allergen.

Long term treatment
Up to two puffs (200 micrograms) 4 times a day.

Children under the age of 12 years

To relieve asthma
One puff (100 micrograms). Your doctor may increase this to two puffs (200 micrograms) if required.

To prevent asthma
One puff (100 micrograms) 10-15 minutes before exercise or exposure to a recognised allergen. Your doctor may increase this to two puffs if required.

Long term treatment
Up to two puffs (200 micrograms) 4 times a day.

The maximum dose is 8 puffs (800 micrograms) in a 24 hour period.

Instructions for use
- Ventolin Evohaler produces a fine mist which you inhale through your mouth into your lungs. Your doctor, nurse or pharmacist should show you how to use your inhaler. If you are not sure, ask your doctor, nurse or pharmacist.
- Each Evohaler canister provides 200 puffs.

Do not use your inhaler more often than the doctor told you to. Tell your doctor **promptly** if your medicine does not seem to be working as well as usual **(for example you need higher doses to relieve your breathing problems or your inhaler fails to give rapid relief with a duration of at least 3 hours following administration)** as your chest problem may be getting worse and you may need a different medicine.

Tell your doctor if your asthma gets worse or if this medicine does not provide as much relief from your asthma as before.

If you use Ventolin Evohaler more than twice a week to treat your asthma symptoms, not including preventive use before exercise, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma) that can have serious complications and may be life-threatening or even fatal. You should contact your doctor as soon as possible to review your asthma treatment.

If you use a medicine against inflammation of your lungs daily, e.g., “inhaled corticosteroid”, it is important to continue using it regularly, even if you feel better.

Your doctor may have told you to take more than this as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you keep to your doctor's instructions as to how many puffs to take and how often to use your inhaler.

Testing your inhaler

1 When using the 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 canister to release two puffs into the air. If you have not used the inhaler for 5 days or more, release two puffs of medicine into the air.

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 shown in the first picture). Check inside and outside to make sure that the mouthpiece is clean and free of objects.

3 Shake the inhaler 4 or 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. Do not breathe in again yet.



5 Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.



6 Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister 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 If your doctor has told you to take two puffs, wait about half a minute before you take another puff by repeating steps 3 to 7.

9 After use always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position.

Practise in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth you should start again.

Some people may find it difficult to release a puff of medicine just after they start to breathe in. A spacer device helps overcome this problem. Your doctor, nurse or pharmacist will be able to advise you.

Young children may need help and their parents may need to operate the inhaler for them. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practise the technique together. You may find the Babyhaler device useful if you have to give Ventolin Evohaler to a baby or a child under 5 – speak to your doctor if you think you might need one of these.

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. If this does not help, your doctor, nurse or pharmacist will be able to advise you.

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 metal canister from the plastic casing.
- Remove the mouthpiece cover.
- Rinse the plastic casing under warm running water.
- Dry the plastic casing thoroughly inside and out.
- Replace the metal canister and the mouthpiece cover. Do not put the metal canister in water.

If you take more Ventolin Evohaler than you should
If you take more than you should, talk to a doctor as soon as possible.
The following effects may happen:
- your heart beats faster than usual
- you feel shaky
- hyperactivity
- acid builds up in your body which may cause your breathing to become faster. These effects usually wear off in a few hours.

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

If you stop taking Ventolin Evohaler
Do not stop taking Ventolin Evohaler without talking to your doctor.

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

Possible side effects

If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic Reactions (may affect up to than 1 in 10,000 people)
If you have an allergic reaction, stop taking Ventolin Evohaler and see a doctor straight away. Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

Talk to your doctor as soon as possible if:
- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while
- you may feel your heartbeat is uneven or it gives an extra beat
- these affect less than 1 in 10 people.

If any of these happen to you, talk to your doctor as soon as possible. **Do not stop using this medicine unless told to do so**.

Tell your doctor if you have any of the following side effects which may also happen with this medicine:
Common (may affect up to 1 in 10 people)
- feeling shaky
- headache.

Uncommon (may affect up to 1 in 100 people)
- mouth and throat irritation
- muscle cramps.

Rare (may affect up to 1 in 1,000 people)
- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral vasodilatation).

Very rare (may affect up to 1 in 10,000 people)
- changes in sleep patterns and changes in behaviour, such as restlessness and excitability.

The following side effects can also happen but the frequency of these are not known:
- chest pain, due to heart problems such as angina. Tell your doctor, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.

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:

ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

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

If you think this medicine is not working well enough for you

If your medicine does not seem to be working as well as usual, talk to your doctor as soon as possible. Your chest problem may be getting worse and you may need a different medicine. Do not take extra doses of Ventolin Evohaler unless your doctor tells you to.

How to store Ventolin Evohaler

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Do not refrigerate or freeze.
- Protect from frost and sunlight.
- If the inhaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few minutes before use. Never use anything else to warm it up.
- The metal canister is pressurised. Do not expose to temperatures higher than 50oC. Do not puncture, break or burn the inhaler even when it is empty.
- 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 throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Contents of the pack and other information

What Ventolin Evohaler contains

- The active substance is salbutamol (as sulfate).
- The other ingredient is norflurane.

This medicine contains fluorinated greenhouse gases.
Each inhaler contains 18 g of HFC-134a (also referred as norflurane) corresponding to 0.0257 tonne CO_2 equivalent (global warming potential GWP = 1 430).

What Ventolin Evohaler looks like and contents of the pack

Ventolin Evohaler comprises an aluminium alloy can sealed with a metering valve, actuator and dust cap.
Each canister contains 200 doses of 100 micrograms of salbutamol (as salbutamol sulfate).

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