

Rexair Inhaler

Consumer Medicine Information

Fluticasone Propionate and Salmeterol (as xinafoate)

50 mcg/25 mcg, 125 mcg/25 mcg, 250 mcg/25 mcg suspension for inhalation

120 ACTUATIONS

What is in this leaflet

The information enclosed answers several general questions about your Rexair Inhaler. This leaflet does not include all the accessible information on Rexair Inhaler. All medication has benefits and risks. Your doctor will have considered the risks of you using Rexair 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.

Rexair Inhaler is only available by prescription.

What your Rexair Inhaler is used for

Rexair Inhaler contains Fluticasone propionate which is a steroid and Salmeterol (as xinafoate) which opens the airways.

The corticosteroids in your Rexair Inhaler are not the same as anabolic steroids that have been known to have been exploited by sports people. The anti-inflammatory effect in your medication is due to the corticosteroids.

Salmeterol is a bronchodilator which opens the airways in your lungs. Salmeterol provides support for up to twelve hours.

Each Rexair Inhaler delivers either 50 mcg of fluticasone propionate and 25 mcg of salmeterol (as salmeterol xinafoate); 125 mcg of fluticasone propionate and 25 mcg of salmeterol (as xinafoate); or 250 mcg of fluticasone propionate and 25 mcg of salmeterol (as salmeterol xinafoate) per actuation (or dose). Your Rexair 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 Rexair Inhaler also contains the propellant HFA-134a, less than 0.002g ethanol, and less than 0.00006mg soy lecithin per actuation.

Rexair 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 Rexair 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.

Rexair Inhaler is a "combination" inhaler that opens the airways and reduces swelling and irritation in the air passages in your lungs. If you have asthma, taking Rexair Inhaler regularly every morning and evening will help prevent asthma attacks.

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

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

Before you use your Rexair Inhaler

If you have any concerns or questions about using your Rexair 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 your Rexair Inhaler if you:

- Are allergic to Fluticasone propionate, Salmeterol (as xinafoate) or any of the other ingredients in your inhaler;
- Have been taking or are currently taking steroid tablets or have had a steroid injection;
- Have an allergy to dyes, preservatives, foods or other medication;
- Are pregnant or intending to become pregnant;
- Are breastfeeding;
- Are taking ANY other medicines;
- Have ever had tuberculosis (TB) or another long-term lung infection;
- Have diabetes;
- Have heart disease, including an irregular or fast heart beat;
- Have an overactive thyroid gland;
- Have high blood pressure;
- Have been diagnosed previously with thrush in your mouth;
- Have low potassium in your blood.

Using other medicines

Please tell your doctor, pharmacist or asthma nurse if you are taking, have recently taken or might take any other medicines. This includes medicines for asthma or any medicines obtained without a prescription. This is because Rexair Inhaler 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 Rexair Inhaler:

- β blockers (such as atenolol, propranolol and sotalol). β 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 Rexair Inhaler, 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

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

Using your Rexair Inhaler

To get the full benefit from your Rexair Inhaler, you need to take it regularly in the morning and evening approximately at a similar time each day.

You can take your Rexair Inhaler before or after a meal.

Rexair Inhaler comes in three different strengths. Your doctor will have decided which strength you need and how many doses to take. The dispensing label should tell you how much to take and how often.

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.

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

Rexair Inhaler is for oral inhalation only.

It is important that even if you feel that your chest condition has improved, that you do not discontinue using your Rexair Inhaler unless your doctor instructs you to. The medication in your Rexair Inhaler is used to help manage your symptoms however does not treat it.

The usual doses of Rexair Inhaler are:

Adults and adolescents aged 12 years or older

The recommended dosage of Rexair Inhaler in adults or adolescents older than 12 years depends on your severity of the disease and includes:

- Rexair Inhaler 50 mcg/25 mcg (50 mcg fluticasone/25 mcg salmeterol), two inhalations twice a day (taken in the morning and evening).
- Rexair Inhaler 125 mcg/25 mcg (125 mcg fluticasone/25 mcg salmeterol), two inhalations twice a day (taken in the morning and evening).
- Rexair Inhaler 250 mcg/25 mcg (250 mcg fluticasone/25 mcg salmeterol), two inhalations twice a day (taken in the morning and evening).

Children aged 4 to 11 years

The recommended dosage of Rexair Inhaler in children over 4 years of age is 50 mcg/25 mcg (50 mcg Fluticasone/25 mcg Salmeterol), two inhalations twice a day (taken in the morning and evening).

Children aged less than 4 years

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

While you are using your Rexair Inhaler

In the event of an asthma attack, use your “reliever” inhaler (e.g. salbutamol), not your Rexair Inhaler.

Contact your doctor immediately if:

- Your breathing suddenly becomes more difficult just after you have used your Rexair Inhaler;
- The effects of your Rexair 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 Rexair Inhaler.

If you feel that your condition is not improving and you are wheezing more often and feeling breathless, discuss this with your doctor as soon as possible.

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

If you have not used your Rexair Inhaler as exactly as your doctor has prescribed, advise them of this information. If you do not, your doctor may change your

medication unreasonably under the impression that the medicine is not working for you.

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

All health providers should be informed that you are using your Rexair Inhaler due to the steroids in your medication. You may require additional steroids (tablets or injections) at times when your body is stressed, for example, an accident, serious infection or if you are having an operation.

Rexair Inhaler may interfere with blood test results. If you are required to have a blood test advise your doctor that you have been prescribed Rexair Inhaler prior to the blood test.

It is advised that if you have been prescribed Rexair Inhaler along with steroid tablets that you should carry a steroid warning card with you in the event that extra oral steroids are required during times of stress.

Make sure you attend all doctor's appointments in relation to your asthma or COPD so that your control and management of your condition can be reviewed.

If you forget to use your Rexair 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 Rexair 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 Rexair 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 Rexair Inhaler (overdose):

If you or someone else takes too much of your Rexair 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.

Possible overdose symptoms can include an increased breathing rate, headache, higher blood glucose levels, considerable muscle tremor, increase in blood pressure, and a faster heartbeat.

Side effects

If you experience any of the following side effects, stop taking Rexair 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;
- Tightness of the chest.

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

Other side effects are:

- Headache - this usually gets better as treatment continues;
- Rash;
- Bruising;
- Thrush in the mouth and throat causing a hoarse voice and throat irritation. Rinsing your mouth out with water and spitting it out immediately after taking a dose of Rexair Inhaler may help;
- Aching, swollen joints and muscle pain;
- Muscle cramps;
- Pneumonia and bronchitis (lung infection); Increases in the amount of sugar (glucose) in your blood (hyperglycaemia);
- Very fast heart beat (tachycardia), or a rapid and irregular heartbeat (atrial fibrillation);
- Feeling shaky (tremor) and fast or uneven heart beat (palpitations);
- Feeling worried (this effect mainly occurs in children);
- Disturbed sleep;
- Rexair 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:
 - o Slowing of growth in children and adolescents
 - o Thinning of the bones
 - o Glaucoma
 - o Cataract (cloudy lens in the eye).
 - o Rounded (moon shaped) face (Cushing's Syndrome)
 - o Behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).

If steroids are taken over a long time and at a high dosage it can result in the adrenal glands being affected as they make their own steroids for the body. Tests may be conducted by your doctor to see how your adrenal glands are functioning. Please discuss any concerns with your doctor.

Rexair Inhaler contains medication that is not addictive.

After using your Rexair Inhaler

Storage and disposal

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

Store Rexair Inhaler below 25°C.

The shelf life of Rexair 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 Rexair 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 Rexair Inhaler in your car on a hot day or on a window sill. Protect your Rexair 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

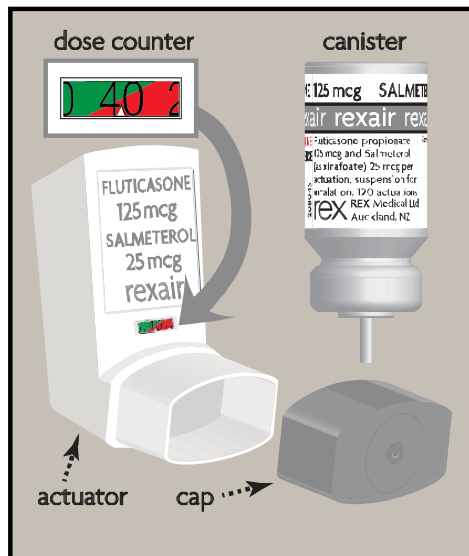
If the doctor advises you to stop taking Rexair Inhaler, or it has exceeded its expiry date, request information from your pharmacist on what to do with any product that is left over.

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

Instructions for Use

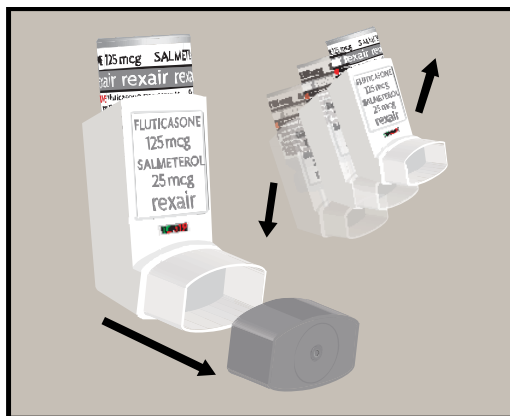
Correct operation of the Rexair Inhaler is essential for successful therapy.

PARTS OF THE INHALER



All strengths of Rexair Inhaler have the same instructions for handling, use and cleaning.

Prior to using the Rexair 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 Rexair 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. **Rinse your mouth with water after inhalation and spit it out.**
7. **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.

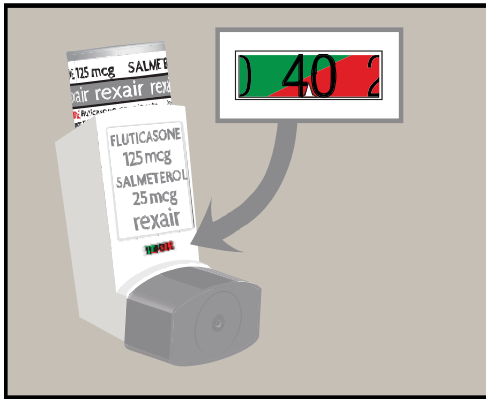
Provide feedback to your doctor if you have any concerns or issues when using your Rexair Inhaler. If different directions have been provided by your doctor, please follow these instructions with care.

Built-in Dose Counter

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

After Rexair 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 Rexair Inhaler, the colour on the dose counter will change from green to red.



When the dose counter on the Rexair 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 Rexair Inhaler may not feel empty and may continue to operate; however, the right amount of medicine may not be dispersed 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 Rexair 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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