

NEW ZEALAND CONSUMER MEDICINE INFORMATION

RESPIGEN™



Salbutamol (as sulfate) 100 micrograms per actuation inhalation aerosol

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may want to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not give it to anyone else. It may harm them, even if their symptoms are the same as yours.

Your medicine

Your medicine is in the form of a pressurised inhalation aerosol. Each *actuation* (puff) from the aerosol contains 100 micrograms of the active ingredient salbutamol (as salbutamol sulfate). The aerosol also contains the CFC-free propellant, HFA-134a, oleic acid and ethanol.

The active ingredient in this medicine, salbutamol, is exactly the same as in your previous salbutamol inhaler, and to help protect the environment, this product does not contain any chlorofluorocarbon (CFC) propellants. This medicine contains a **CFC-free propellant, 1,1,1,2-tetrafluoroethane, also known as propellant HFA-134a** and because of this you might notice that the medicine tastes different, or that the spray feels different in your mouth or that the inhaler sounds different when it is used. This does not affect the way in which your inhaler works.

Respigen 100 micrograms per actuation pressurised inhalation suspension is supplied as a single inhaler that contains a minimum of 200 actuations (200 puffs).

What Respigen Inhaler is and what it is used for

Your inhaler contains salbutamol which belongs to a group of medicines called short-acting B₂ agonists, bronchodilators or “relievers”. Salbutamol acts directly on the muscles in the airways of the lung causing the muscles to relax. This widens or opens up the airways of your lungs. Salbutamol is used by patients in whom a diagnosis of asthma has been made as it relieves the symptoms of asthma.

Salbutamol can also be used to relieve symptoms such as chest tightness, wheezing, shortness of breath and coughing in some other chest diseases.

Respigen Inhaler can also be used to prevent asthma symptoms which occur with exercise or on exposure to an allergen, such as cat or dog fur, pollen or house dust.

You may also be using another inhaler regularly to help prevent asthma attacks, such as a corticosteroid inhaler (ie. beclometasone dipropionate). This inhaler is known as a “preventer”. You can safely use your “preventer” inhaler with Respigen Inhaler. However, **BEFORE** using Respigen Inhaler, it is important to let your doctor know if you are on any other medication, including any inhalers.

Unlike salbutamol injection (and occasionally tablets), inhaled salbutamol cannot be used to treat premature labour or threatened miscarriage.

Before using your Respigen Inhaler

Do not use your Respigen Inhaler if:

- you know you are allergic to salbutamol or any of the other ingredients
- you are pregnant, think you may be pregnant or intend to become pregnant (unless agreed by your doctor)

- or you are breast-feeding (unless agreed by your doctor).

Tell your doctor or pharmacist if:

- you are being treated for an overactive thyroid (thyrotoxicosis)
- you are being treated for high blood pressure
- you have a history of heart disease, irregular heart rhythm or angina
- you are taking **any** other medicines (including inhalers) but particularly the following:
 - corticosteroids eg. beclometasone dipropionate for your asthma
 - diuretics (“water” tablets)
 - medicine to reduce blood pressure eg. atenolol
 - medicines to control an irregular heart beat/rhythm, or very fast pulse
 - tablets prescribed for your asthma to help your breathing, eg. theophylline or aminophylline.

How to use your Respigen Inhaler

Respigen Inhaler sprays a fine cloud of drug particles which you breathe in (inhale) through your mouth into your lungs. It is important that you know how to use your inhaler properly. Instructions on how to do this are given below. If you encounter any problems ask your doctor, nurse or pharmacist.

Your doctor should have told you HOW and WHEN to use your inhaler and HOW MANY puffs to inhale. This information should also be on the pharmacists’ label. If you are unsure about any aspect of HOW, WHEN or HOW MANY puffs to take of your medicine then ask your doctor, nurse or pharmacist.

Dosage

To relieve asthma symptoms such as wheezing, breathlessness and tightness in your chest, and including bronchospasm, the usual dose is as follows:

Adults and the elderly: Take one puff to relieve asthma symptoms. This may be increased to 2 puffs if required. For optimum benefit Respigen Inhaler should be used as required.

You should not take more than 8 puffs in 24 hours and 2 puffs should not usually be taken more often than every 4 hours (up to a maximum total daily dose of 8 puffs only). If you find that you need to use Respigen Inhaler regularly every day or you notice that you are needing to use your Respigen Inhaler more frequently than normal, this may mean that your asthma is not very well controlled or is getting worse. You should contact your doctor or your asthma nurse straightaway.

If Respigen Inhaler fails to give you at least 3 hours relief, tell your doctor as soon as possible.

To prevent the symptoms of asthma which occur during exercise or following exposure to an allergen, take 2 puffs about 15 minutes before exercise or exposure to allergens.

Children: Take one puff to relieve asthma symptoms. This may be increased to 2 puffs if required. For optimum benefit Respigen Inhaler should be used as required.

As with adults your child should not take more than 8 puffs in 24 hours and 2 puffs should not usually be taken more often than every 4 hours (up to a maximum total daily dose of 8 puffs only). If you find your child needs to use Respigen Inhaler regularly every day or you notice that your child needs to use their Respigen Inhaler more frequently than normal, this may mean that your child’s asthma is not very well controlled or is getting worse. You should contact your doctor or the asthma nurse straightaway.

To prevent the symptoms of asthma which occur during exercise or following exposure to an allergen, take one puff about 15 minutes before exercise or exposure to allergens. If one puff does not provide relief from the symptoms of exercise or allergen exposure this dose can be increased to 2 puffs.

The above doses are described as *usual doses*. However, all patients are different, and your doctor may have prescribed a different dose for you.

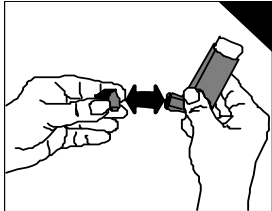
Always remember:

- **YOU MUST NOT** use your inhaler more often than your doctor told you to.
- **YOU MUST NOT stop using your inhaler unless your doctor tells you to stop.**

- You may be told to take more puffs than usual as emergency treatment if your breathing or wheezing is very bad. IT IS VERY IMPORTANT to follow your doctor's instructions on HOW, WHEN and HOW MANY puffs of your medicine to take.
- Should you visit another doctor, a dentist, or go to hospital, take ALL your medicines and inhalers with you, including any medicines or tablets you have bought without a prescription from the pharmacy, and all in their original packaging if possible.

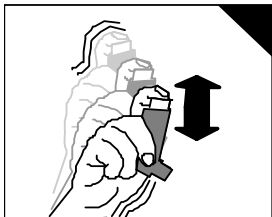
Instructions for use

1. Remove the cap from the mouthpiece by holding it between thumb and forefinger and squeezing gently whilst pulling them apart. Check that there are no objects in the mouthpiece and that it is clean.

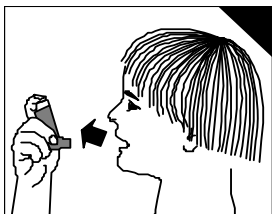


Testing your Respigen Inhaler - If the inhaler is new, or has not been used for more than one week, shake it well and fire two puffs into the air to check that it works.

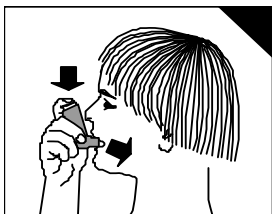
2. Hold the inhaler upright with your thumb on the base and your first finger on the top of the can, as shown in the diagram and shake well.



3. Breathe out slowly through your mouth as far as is comfortable and then immediately place the mouthpiece fully into your mouth and close your lips lightly around it, but do not bite it.



4. Breathe in slowly and deeply and as you start to do so press the metal canister down firmly with your first finger to spray the aerosol and release the medicine. Continue to breathe in steadily and deeply.



5. Hold your breath and remove the mouthpiece from your mouth. Continue to hold your breath for about 10 seconds, or as long as comfortable, then breathe out slowly.



6. Wait for about one minute before taking another puff, if needed. Then repeat steps 2 to 5.
7. Replace the cap on the mouthpiece by snapping it into place to protect the mouthpiece from dirt and dust.

It is VERY important that you do not rush steps 3 and 4.

It is very important that you breathe in slowly before pressing the metal canister. It is a good idea to practice this in front of a mirror. If you see mist coming from your mouth or the inhaler then you should repeat the instructions from step 2. However do not have more than 4 goes at this whilst practising.

If you have difficulty in operating the inhaler with one hand, it is possible to use both hands. At step 2, put both forefingers on top of the canister and place both thumbs on the base. Then proceed as instructed.

Some people find it difficult to press their inhaler and breathe in at the same time. A spacer device helps to overcome this problem. If you use a spacer device please follow the instructions provided with it specifically in respect of cleaning the device prior to first use and subsequent cleaning. Your doctor, nurse or pharmacist will be able to advise you about your use of the spacer device. The use of a spacer device may alter the amount of salbutamol which goes into your lungs and ends up in your blood. If you notice any side effects such as tremor or a rapid or irregular heart beat (palpitations) you should tell your doctor before you use your inhaler with the spacer device again. Your doctor may need to change the dose of Respigen Inhaler or may change your treatment altogether.

Your doctor may give you different instructions to these on how to use your inhaler. If so please follow them. If you have any difficulties in using this inhaler please tell your doctor, nurse or pharmacist.

After taking your medicine

If your breathing or wheezing gets worse immediately after using your inhaler STOP USING IT IMMEDIATELY. Tell your doctor immediately. You may need a different “reliever” medicine to treat your symptoms.

If you notice that the relief of your chest tightness or wheezing is not as good as it was or does not last as long as usual then tell your doctor as soon as possible. It is possible that your asthma is getting worse and you need other medicines to help treat it.

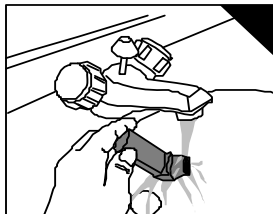
If you take too much of your medicine

If you take more puffs than you have been told to take you may notice that you feel shaky and that your heart is beating faster than normal. These effects usually wear off without treatment. However, you should still tell your doctor as soon as possible.

Cleaning

You should clean your inhaler once a week. To clean it:

1. Remove the metal canister by gripping it firmly and pulling it out of the plastic case. Then remove the dust cap from the case.
2. Clean the mouthpiece and dust cap in warm water. You can also add a mild detergent or baby bottle cleaning solution to the water, your pharmacist can advise you about this. If you use a cleaning solution rinse the plastic case and dust cap in running water. **DO NOT** put the metal canister into water.



3. Dry the case and dust cap in a warm place, but avoid direct heat.
4. Replace the dust cap and metal canister by reversing step 1.

Possible side effects

Most people do not suffer from any problems when taking this medicine. However, as with all medicines, some people can experience unwanted effects.

Some people notice a slight shaking, most noticeably of the hands or they have a headache.

Some people may be very sensitive to Respigen Inhaler and notice their heart beating faster than normal (palpitations) or feel their heartbeat is irregular or that there seem to be extra beats. Patients may feel flushed. If you experience any of these symptoms you must contact your doctor immediately, but do not stop taking your medicine unless instructed to do so.

Although it is not known exactly how often this happens, some people may occasionally experience chest pain (due to heart problems such as angina). Tell your doctor if you develop these symptoms whilst receiving treatment with Respigen, but do not stop using this medicine unless instructed to do so.

Inhaled salbutamol sometimes causes irritation in the mouth and/or throat.

Very rarely Respigen Inhaler can cause allergic reactions and the following might occur:

- swelling of the face, eyes, tongue, lips or throat (also known as angioneurotic oedema)
- an allergic skin rash which is red and itchy and/or patchy and swollen (also known as urticaria)
- difficulty breathing
- low blood pressure – you may feel light-headed or dizzy
- collapse.

Respigen Inhaler may alter the salt balance in your body and therefore your doctor may take a blood sample to check your potassium levels from time to time.

Very rarely muscle cramps have been reported.

Children using a Respigen Inhaler may become restless or excitable; however, these unwanted effects are rare.

If you should suffer from any of these unwanted effects or any other undesired effect please tell your doctor or pharmacist as soon as possible.

Storing your Respigen Inhaler

Store below 25°C. Protect from light and frost.

The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn, even when apparently empty.

Do not freeze or refrigerate Respigen. If your Respigen Inhaler gets very cold, remove the metal canister from the plastic case and warm it by rolling between your hands. **DO NOT USE ANY OTHER SOURCE OF HEAT TO WARM IT UP.**

DO NOT USE THIS MEDICINE AFTER THE EXPIRY DATE SHOWN ON THE LABEL.

KEEP OUT OF REACH AND SIGHT OF CHILDREN

Return any unused or partly used and unwanted Respigen Inhalers to your pharmacist for disposal.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of information

16 August 2011
(Based on datasheet 16 August 2011)