

## RESPIGEN®

### *Salbutamol (as sulfate) 100 micrograms per actuation inhalation aerosol*



## What is in this leaflet

Please read this leaflet carefully before you start using Respigen.

This leaflet answers some common questions about Respigen.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Respigen against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

## What RESPIGEN is used for

Respigen helps you to breathe more easily. When your chest is tight or when you are wheezing, the medicine opens up the breathing tubes in your lungs. Your medicine is known as a bronchodilator.

Because Respigen gives fast relief from your chest symptoms, it is often called a 'reliever puffer'. Some people start wheezing or their chest starts to feel tight when they exercise. This is called exercise-induced asthma. If you have exercise-induced asthma, your doctor may tell you to take one or two puffs of your Respigen inhaler before you exercise. This can help to prevent the symptoms of exercise-induced asthma.

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.

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

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.

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

Your inhaler contains salbutamol which belongs to a group of medicines called short-acting B<sub>2</sub> agonists, bronchodilators or "relievers".

You may also be using another inhaler regularly to help prevent asthma attacks, such as a corticosteroid inhaler (i.e. 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.

Your doctor may have prescribed this medicine for another reason.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

This medicine is available only with a doctor's prescription.

## Before you use RESPIGEN

### *When you must not use it*

**Do not use Respigen if you have an allergy to:**

- any medicine containing salbutamol sulfate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not use this medicine if you are pregnant, think you may be pregnant or intend to become pregnant (unless agreed by your doctor).**

**Do not breast-feed if you are taking this medicine (unless agreed by your doctor).**

The active ingredient in Respigen may pass into breast milk and there is a possibility that your baby may be affected.

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

**Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start using this medicine, talk to your doctor.**

## **Before you start to use it**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- overactive thyroid (thyrotoxicosis)
- high blood pressure
- a history of heart disease, irregular heart rhythm or angina
- liver problems
- kidney problems

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before you start using Respigen.**

## **Taking other medicines**

**Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.**

You should also tell any health professional who is prescribing a new medication for you that you are using Respigen.

Some medicines may interfere with Respigen. These include:

- corticosteroids e.g., beclometasone dipropionate for your asthma
- diuretics ("water" tablets)
- medicines used to treat high blood pressure such as atenolol or propranolol
- medicines such as xanthine derivatives used to treat bronchospasm, asthma, chronic bronchitis and emphysema (e.g. theophylline)

These medicines may be affected by Respigen or may affect how well it

works. You may need different amounts of your medicines, or you may need to use different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

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## **How to use RESPIGEN**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

Respigen Inhaler sprays a fine cloud of medicine 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.

## **How much to use**

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.**

## How to use it

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.

### ***How long to use it***

**Continue using your medicine for as long as your doctor tells you.**

This medicine helps to control your condition, but does not cure it.

### ***If you forget to use it***

**If you forget a dose, do not worry, just take the next dose at the normal time or earlier if you become wheezy or tight in the chest.**

**Do not use a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

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## **While you are using RESPIGEN**

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### ***Things you must do***

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Respigen.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.** It may affect other medicines used during surgery.

**If you become pregnant while using this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are using this medicine.**

It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

### ***Things you must not do***

**Do not use Respigen to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop using your medicine or lower the dosage without checking with your doctor.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how Respigen affects you.**

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

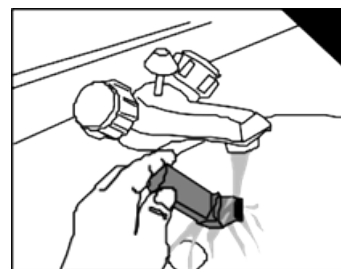
Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

### ***Cleaning your Inhaler***

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.

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## **In case of overdose**

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### ***If you use too much (overdose)***

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have used too much Respigen. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Respigen.**

This medicine helps most people, but it may have unwanted side effects in a few people.

**All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- Tremor
- Headache
- Hyperactivity
- Mouth and throat irritation
- Muscle cramps

**Tell your doctor as soon as possible if you notice any of the following:**

- Fast heart-beat
- Irregular heart-beat

The above list includes serious side effects that may require medical attention.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

In a few people, the medicine may affect your blood-potassium levels. Your doctor may do tests to check this.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

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## After using RESPIGEN

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### Storage

**Keep your inhaler in the pack until it is time to use it.**

**Keep your inhaler in a cool dry place where the temperature stays below 25°C.**

**Protect from frost and direct sunlight.**

**The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C.**

**As with most inhaled medications in aerosol canisters, the therapeutic effect of this medication may decrease when the canister is cold. Do not freeze or refrigerate.**

**The canister should not be broken, punctured or burnt, even when apparently empty.**

Do not store Respigen or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

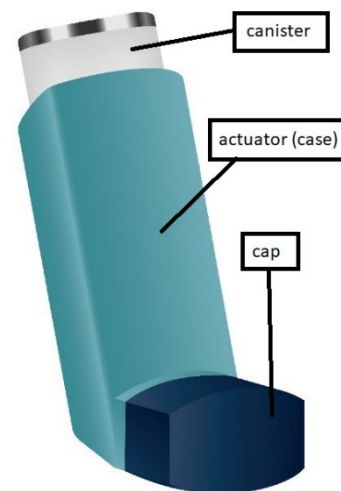
**If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

### Recycling information

**The box/carton and leaflet can both be recycled.**

**The cap and actuator (case) are produced from Number 5 Polypropylene (PP). Check with your local recycling centre whether these will be accepted.**

**The empty canister should be disposed of.**



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## Product description

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### What it looks like

Respigen consists of a white microfine suspension of salbutamol in a non-CFC liquid propellant mixture packed under its own vapour pressure in an aluminium can sealed with a metering valve.

### Ingredients

#### Active ingredient(s):

Respigen contains 100 micrograms of salbutamol (as sulfate) as the active ingredient.

#### Inactive ingredient(s):

Respigen also contains:

- 1,1,1,2-tetrafluoroethane (also known as HFA 134a or norflurane)
- Oleic acid
- ethanol

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## If you want to know more

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

## ***Who supplies this medicine***

Respigen is supplied in New Zealand by:

Viatriis Ltd  
PO Box 11-183  
Ellerslie  
AUCKLAND

[www.viatriis.co.nz](http://www.viatriis.co.nz)

Telephone 0800 168 169

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## **Date of Preparation**

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26 May 2022.

(Based on datasheet dated 26 May 2022)

RESPIGEN® is a Viatriis company trade mark.