

ZEMPREON[®] CFC-FREE INHALER (with counter)

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ZEMPREON INHALER?

ZEMPREON INHALER contains the active ingredient salbutamol sulfate. ZEMPREON INHALER, which you may know better as a 'puffer', helps you to breathe more easily.

For more information, see Section [1. Why am I using ZEMPREON INHALER?](#) in the full CMI.

2. What should I know before I use ZEMPREON INHALER?

Do not use if you have ever had an allergic reaction to salbutamol sulfate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ZEMPREON INHALER?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZEMPREON INHALER and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ZEMPREON INHALER?

- For adults, the usual dose is one or two puffs, as required, repeated four hourly.
- For children, the usual dose is one puff, repeated four hourly. The dose may be increased to two puffs, repeated four hourly, if required.

More instructions can be found in Section [4. How do I use ZEMPREON INHALER?](#) in the full CMI.

5. What should I know while using ZEMPREON INHALER?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are
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	<p>using ZEMPREON INHALER.</p> <ul style="list-style-type: none"> ● Contact your doctor if you become concerned about any side effects. ● Tell your doctor immediately, if you become or intend to become pregnant while using ZEMPREON INHALER and stop using it immediately. ● Your doctor may tell you to take extra puffs of ZEMPREON INHALER if your wheezing or breathing suddenly gets worse. If you take extra puffs and do not get relief, tell your doctor immediately.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not take any other medicines to help you breathe without checking with your doctor. ● You should not give this medicine to anyone else, even if their symptoms seem similar to yours

	<ul style="list-style-type: none"> • Do not use ZEMPREON INHALER if the counter shows 000 or if the expiry date has passed.
Looking after your medicine	<ul style="list-style-type: none"> • Store ZEMPREON INHALER below 30°C. • Clean ZEMPREON INHALER at least once a week. • Do not put the metal canister in water. • Do not put it in the refrigerator. • Do not expose to temperatures higher than 50°C. • Do not burn it or puncture it, even when it is empty.

For more information, see Section [5. What should I know while using ZEMPREON INHALER?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include headache, tremor, feelings of anxiety, restlessness, or excitability, 'warm' feeling or flushing, restlessness in children, mouth or throat irritation, muscle cramps and nausea. Serious side effects include allergic reactions, irregular or fast heartbeat, immediate breathing difficulties and

wheezing, changes in blood potassium levels and lactic acidosis.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ZEMPREON® CFC-FREE INHALER (with counter)

Active ingredient(s): *salbutamol sulfate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZEMPREON INHALER. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZEMPREON INHALER.**

Where to find information in this leaflet:

- [1. Why am I using ZEMPREON INHALER?](#)
- [2. What should I know before I use ZEMPREON INHALER?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ZEMPREON INHALER?](#)
- [5. What should I know while using ZEMPREON INHALER?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ZEMPREON INHALER?

ZEMPREON INHALER contains the active ingredient salbutamol sulfate. Salbutamol sulfate belongs to a group of medicines called bronchodilators . Because your ZEMPREON INHALER gives fast relief from your chest symptoms, it is often called a 'reliever'.

ZEMPREON INHALER is used for the relief of bronchospasm in patients with asthma or chronic obstructive pulmonary disease (COPD), and for relief against exercise-induced asthma and other stimuli known to induce bronchospasm.

Bronchodilators relax the muscles of the small air passages in the lungs within a few minutes. This helps to open the airways and makes it easier for air to get in and out of the lungs. When it is used regularly, it helps the small air passages to remain open.

There are other types of medicines that prevent wheezing or chest tightness. These medicines are called 'preventers' and must be used every day. Your doctor may tell you to use a 'preventer' in addition to ZEMPREON INHALER.

Ask your doctor if you have any questions about why you are using this medicine.

2. What should I know before I use ZEMPREON INHALER?

Warnings

When the dose counter reading approaches zero, contact your doctor or pharmacist to get a new inhaler.

Any puffs left in the device after the dose counter reads zero (000) are not enough to give you the right dose of salbutamol, so you cannot be sure you will receive any medicine after using 200 puffs.

Consider keeping a back-up inhaler.

Do not use ZEMPREON INHALER if:

- you have an allergy to salbutamol sulfate, or 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

Always check the ingredients to make sure you can use this medicine.

- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Do not use ZEMPREON INHALER to stop a miscarriage or premature labour.

Check with your doctor or pharmacist if you:

- have any other medical conditions
- take any medicines for any other condition
- have had to stop taking this or any other asthma medicine
- are allergic to any medicine
- have been diagnosed with, or are being treated for:
 - a thyroid problem
 - high blood pressure
 - a heart problem
 - a liver problem
 - a kidney problem
 - diabetes or high blood sugar
- are breastfeeding, pregnant or trying to become pregnant.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant or if you are breastfeeding or intend to breastfeed.

ZEMPREON INHALER is not usually recommended for use during pregnancy. Your doctor will weigh up the benefits to you against the potential risks to your baby when considering the use of ZEMPREON INHALER during your pregnancy.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

It is not known whether the ingredients of ZEMPREON INHALER can pass into breast milk.

3. What if I am taking other medicines?

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

Some medicines may interfere with ZEMPREON INHALER and affect how it works or make it more likely that you will have side effects.

These medicines include:

- xanthine derivatives (such as theophylline) or steroids to treat asthma.
- diuretics (also called water tablets), sometimes used to treat high blood pressure or a heart condition.
- beta-blockers used to treat high blood pressure or a heart condition.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZEMPREON INHALER.

4. How do I use ZEMPREON INHALER?

How much to use

Always use ZEMPREON INHALER exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

ZEMPREON INHALER should be used as required rather than regularly.

If you are using ZEMPREON INHALER more than twice a week to treat your asthma symptoms, not including preventive use before exercise or other triggers, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma). You should contact your doctor as soon as possible to review your asthma treatment.

If you use your asthma anti-inflammatory medicine daily, e.g., "inhaled corticosteroid", it is important to continue using it regularly, even if you feel better.

Adults

- To relieve asthma symptoms/attack, the usual dose for adults is one or two inhalations repeated four hourly.

- To prevent asthma symptoms/attack, the usual dose for adults is two puffs 10 to 15 minutes before exercise or exposure to a "trigger".
- Your doctor may tell you to take extra puffs of ZEMPREON INHALER if your chest condition suddenly gets worse. If you take extra puffs and do not get relief, tell your doctor immediately.
- Initial doses in the elderly may be lower than the recommended adult dose.

Children

- To relieve asthma symptoms/attack, the usual dose for children is one inhalation, as required, repeated four hourly, or as directed by their doctor or pharmacist. The dose may be increased to two inhalations if required.
- To prevent asthma symptoms/attack, the usual dose for children is one inhalation 10 to 15 minutes before exercise or exposure to a "trigger". The dose may be increased to two inhalations if required.

How to use ZEMPREON INHALER

- If ZEMPREON INHALER is new and you have not used it before, release four puffs into the air until the counter reads 200 to make sure that it works.
- If you have not used it for 5 days or more, or, if you drop the inhaler, you should shake it well, point the mouthpiece away from you and release two puffs into the air before use to make sure that it works.
- Each time the inhaler is activated, the number on the counter will count down by one. In some cases,

dropping the inhaler may cause the counter to count down.

- When the dose counter reads 000, contact your doctor or pharmacist to get a new inhaler. Any puffs left in the device after the dose counter reads zero (000) are not enough to give you the right dose of the medicine.

Using your inhaler

Follow the instructions on how to use ZEMPREON INHALER in the leaflet provided in the carton.

1. Remove the mouthpiece cover by gently squeezing the sides of the cover.
2. Check inside and outside of the inhaler including the mouthpiece for the presence of loose objects.
3. Shake the inhaler well to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.
4. Hold the inhaler upright between fingers and thumb with your thumb on the base, below the mouthpiece.
5. Breathe out as far as is comfortable and then place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it.
6. Just after starting to breathe in through your mouth, press down on top of the inhaler to release salbutamol while still breathing in steadily and deeply.
7. While holding your breath, take the inhaler from your mouth and take your finger from the top of the inhaler. Continue holding your breath for as long as is comfortable.

8. If you are to take further puffs, keep the inhaler upright and wait about half a minute before repeating steps 3 to 7.
9. Replace the mouthpiece cover by firmly pushing and snapping the cap into position.

How to clean your ZEMPREON INHALER

ZEMPREON INHALER should be cleaned at least once a week. You may not see any medicine build-up on the inhaler, but it is important to keep it clean so medicine build-up will not block the spray.

1. Remove the metal canister and dose counter from the plastic casing (actuator) of the inhaler and remove the mouthpiece cover.
2. Rinse the actuator thoroughly under warm running water.
3. Turn the actuator upside down and rinse again through the mouthpiece thoroughly under warm running water.
4. Shake off as much water from the actuator as you can. Look into the mouthpiece to make sure any medicine build-up has been completely washed away. If there is any build-up, repeat Step 2 and Step 3.
5. Dry the actuator thoroughly inside and out (such as overnight).
6. Replace the metal canister and the mouthpiece cover.

DO NOT put the metal canister in water.

If you forget to use ZEMPREON INHALER

ZEMPREON INHALER should be used as required. If you forget to take a dose, do not worry. Just take the next dose at the normal time or earlier if you become wheezy or feel tight in the chest.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting unwanted side effects.

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

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

If you use too much ZEMPREON INHALER

If you think that you or anyone else has used too much of ZEMPREON INHALER, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may notice that your heart is beating faster than usual, you feel shaky or have a headache.

5. What should I know while using ZEMPREON INHALER?

Things you should do

- Remind any doctor, dentist, pharmacist, or healthcare professional you visit that you are using ZEMPREON INHALER, especially if you are about to be started on any new medicine.
- Keep all your doctor's appointments so that your progress can be checked.
- Visit your doctor or pharmacist regularly to check that you are using ZEMPREON INHALER in the right way. If you are not breathing the medicine in correctly, the medicine may not be helping you as much as it could.
- Talk to your doctor or pharmacist if you find it difficult to breathe in and press ZEMPREON INHALER at the same time. It may be better for you to use something called a spacer device with ZEMPREON INHALER. Your doctor or pharmacist will explain what this is and how to use it.
- If you change the make of spacer you use this may alter the amount of drug delivered to the lungs. You should let your doctor know if your asthma symptoms worsen.
- If your asthma worsens (for example you have frequent symptoms or flare ups such as breathlessness, cough, wheezing, tight chest,

nighttime awakening or limited physical ability), you should tell your doctor who may start or increase a medicine to control your asthma such as an inhaled corticosteroid.

Call your doctor straight away if you:

- become pregnant while using this medicine.
- feel that your breathing suddenly becomes more difficult just after you have used your ZEMPREON INHALER
- feel that ZEMPREON INHALER does not help your breathing as much as usual
- feel that the effect of ZEMPREON INHALER does not last as long as usual or lasts less than 3 hours
- need more puffs of your ZEMPREON INHALER to get relief.

Action Plan

If you feel that ZEMPREON INHALER is not having the same effect as before, this may be a sign that your chest condition is getting worse. Your doctor may decide to add another medicine to your treatment.

Things you should not do

- Your ZEMPREON INHALER is only for you. You should not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use your ZEMPREON INHALER if the counter shows 000 or if the expiry has passed. When

the counter shows 000 you must dispose of your ZEMPREON INHALER.

- Never try to alter the numbers on the counter or detach the counter from the metal canister. The counter cannot be reset and is permanently attached to the canister.
- Do not use ZEMPREON INHALER to treat any other complaints unless your doctor tells you to.

Driving or using machines

ZEMPREON INHALER is not expected to have any effect on your ability to drive or use machines.

Looking after your medicine

Straight after use, replace the mouthpiece cover firmly and click it into position.

Keep ZEMPREON inhaler in a place where temperature stays below 30°C.

Keep ZEMPREON INHALER away from frost.

Follow the instructions in the carton on how to take care of your medicine properly.

Store in a cool dry place away from moisture, heat, or sunlight; for example, do not store:

- in the bathroom or near a sink
- in the car or on windowsills
- in the refrigerator.

If your ZEMPREON INHALER becomes very cold, it may not work properly. To warm it, pull out the metal canister from its plastic holder and warm it in your hand for a few minutes. Do not warm the canister in any other way. Push the canister firmly back into its holder before using.

Keep your ZEMPREON INHALER in a place 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.

WARNING: The metal canister is pressurised. Do not expose to temperatures higher than 50°C. Do not burn it or puncture it, even when it is empty.

When to discard your medicine

You will find an expiry (or use by) date on the label of the metal canister. Do not use your ZEMPREON INHALER after this date.

You can recycle the plastic casing and cap of your ZEMPREON INHALER with other plastic items. The plastic casing (actuator) is manufactured from polypropylene.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by the following list of side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• headache• nausea• feelings of anxiety, restlessness or excitability• tremor, shaky or tense feeling• 'warm' feeling or flushing• mouth or throat irritation• muscle cramps• restlessness in children	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reactions:</p> <ul style="list-style-type: none"> • shortness of breath • wheezing, coughing or difficulty breathing • swelling of the face, lips/ mouth, tongue, or throat • rash, itching, redness or hives on the skin • suddenly feeling weak or light headed (may lead to loss of consciousness) <p>Heart related:</p> <ul style="list-style-type: none"> • irregular or fast heart beat • increased blood flow to extremities (hands and feet) <p>Immediate breathing difficulties and wheezing:</p> <ul style="list-style-type: none"> • If your breathing or wheezing gets worse straight after using ZEMPREON 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p data-bbox="248 248 738 465">INHALER, stop using it immediately, and tell your doctor as soon as possible.</p> <p data-bbox="202 490 775 589">Metabolism and nutrition related:</p> <ul data-bbox="202 629 724 1021" style="list-style-type: none"> • Changes in blood potassium levels. This can only be detected when your doctor conducts tests over time to monitor your progress. <p data-bbox="202 1046 564 1093">Lactic acidosis:</p> <ul data-bbox="202 1128 778 1957" style="list-style-type: none"> • This often affects people who have severe kidney disease. • Symptoms of lactic acidosis include some or all of the following: <ul data-bbox="248 1491 767 1957" style="list-style-type: none"> ○ rapid breathing, shortness of breath even though there may be improvement in your wheezing ○ feeling cold ○ stomach pain, nausea and vomiting 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What ZEMPREON INHALER contains

Active ingredient (main ingredient)	salbutamol sulfate
Other ingredients (inactive ingredients)	HFA-134a, a propellant
Potential allergens	ZEMPREON INHALER contains no other additives

Do not take this medicine if you are allergic to any of these ingredients.

Each puff contains 100 micrograms of salbutamol (as sulfate). There are 200 puffs in each ZEMPREON puffer.

What ZEMPREON INHALER looks like

ZEMPREON INHALER (AUST R 335999) consists of a plastic casing which contains a small metal canister. The casing has a mouthpiece which is covered by a cap.

The canister has a counter attached to show how many puffs of medicine you have left. The number of puffs left will show through a window in the back of the plastic casing. Each time the canister is pressed, a puff of the medicine is released and the counter will count down by one.

Who distributes ZEMPREON INHALER

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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