ZEMPREON® CFC-FREE INHALER (with counter)

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 ZEMPREON 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 <u>2. What should I know before I use ZEMPREON INHALER?</u> 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?

- The pharmacist's label will usually tell you how many puffs to take and how often to use your ZEMPREON INHALER. If you are not sure, ask your doctor or pharmacist.
- If your 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, shake it well and release two puffs into the air to make sure that it works.
- Adults and children: As required, one or two puffs, repeated four-hourly.
- Initial doses in the elderly may be lower than the recommended adult dose.

 Your doctor may tell you to take extra puffs of your ZEMPREON INHALER if your chest condition suddenly gets worse. If you take extra puffs and do not get relief, tell your doctor immediately.

More instructions can be found in Section <u>4. How do I</u> use ZEMPREON INHALER? in the full CMI.

5. What should I know while using ZEMPREON INHALER?

Remind any doctor, Things you should do dentist or pharmacist you visit that you are using ZEMPREON INHALER. If your breathing suddenly becomes more difficult just after you have used your ZEMPREON INHALER, tell your doctor immediately You should not give Things you should not this medicine to anyone do else, even if their symptoms seem similar to yours Do not use your ZEMPREON INHALER if the counter shows 000

Looking after your medicine

- Your ZEMPREON INHALER should be cleaned 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 <u>5. What should I know while using ZEMPREON INHALER?</u> in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most common side-effects are headache, nausea, shaky or tense feeling, irregular or fast heart beat, 'warm' feeling and mouth or throat irritation.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> 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. ZEMPREON INHALER is known as a bronchodilator which opens up the breathing tubes in your lungs. 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.

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

Warnings

Do not use ZEMPREON INHALER if:

- you are allergic to salbutamol sulfate, or any of the ingredients listed at the end of this leaflet.
- If you have an allergic reaction (for example skin rash, angioedema (sudden swelling under the skin), or a faint or dizzy feeling) you should stop using your ZEMPREON INHALER and tell your doctor or pharmacist immediately.

- If the expiry date (EXP) printed on the pack has passed.
- If the packaging is torn or shows signs of tampering
- To stop a miscarriage or premature labour.

Check with your doctor if you:

- Are taking any other medicines, including those from the pharmacy and supermarket
- Have had to stop taking this or any other asthma medicine
- Are allergic to any medicine
- Are having treatment for a thyroid problem
- Are having treatment for high blood pressure
- Have, or have had, a heart problem
- Have, or have had, a liver problem
- Have, or have had, a kidney problem
- Have sugar diabetes
- 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 <u>6</u>. 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.

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.

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

- You will find the instructions on how to use your ZEMPREON INHALER in the leaflet provided in the carton.
- As shown in the instruction leaflet, adults or children take one or two inhalations, repeated four hourly if required, or as directed by your doctor or pharmacist. If you are not sure, ask your doctor or pharmacist.
- Initial doses in the elderly may be lower than the recommended adult dose.
- If your 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, shake it well and release two puffs into the air 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.
- Your doctor may tell you to take extra puffs of your ZEMPREON INHALER if your chest condition suddenly gets worse. If you take extra puffs and do not get relief, tell your doctor immediately.
- You should visit your doctor or pharmacist regularly to check that you are using your 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.
- If you find it difficult to breathe in and press your ZEMPREON INHALER at the same time, talk to your doctor or pharmacist. It may be better for you to use something called a spacer device with your 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.

How to clean your ZEMPREON INHALER

Your 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.

- 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

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.

If you use too much ZEMPREON INHALER

You should not take more than the number of puffs that you have been told. If you accidentally take more than recommended, you may notice that your heart is beating faster than usual, and that you feel shaky. You may also have a headache.

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.

5. What should I know while using ZEMPREON INHALER?

Things you should do

Call your doctor straight away if you:

- Your breathing suddenly becomes more difficult just after you have used your ZEMPREON INHALER
- Your ZEMPREON INHALER does not help your breathing as much as usual
- The effect of your ZEMPREON INHALER does not last as long as usual, or lasts less than 3 hours

 You need more puffs of your ZEMPREON INHALER to get relief.

These may be signs that your chest condition is getting worse. Your doctor may decide to add another medicine to your treatment if your ZEMPREON INHALER is not having the same effect as before.

Remind any doctor, dentist or pharmacist you visit that you are using ZEMPREON INHALER.

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. 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.

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 your ZEMPREON INHALER in a place where children cannot reach it.
- Keep your ZEMPREON INHALER away from frost. Do not put it in the refrigerator.
- Keep your ZEMPREON INHALER away from bright sunlight.
- Keep your ZEMPREON INHALER away from heat (store below 30°C). Do not leave it in the car on hot days.
- 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.
- 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 (as relevant)

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.

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.

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
 headache nausea shaky or tense feeling 'warm' feeling mouth or throat irritation. muscle cramps restlessness in children 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
irregular or fast heart beatlow platelet count	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
	notice any of these serious side effects.

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	salbutamol sulfate
(main ingredient)	
Other ingredients	HFA-134a, a propellant

(inactive ingredients)	
1	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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