SEREVENT INHALER (CFC-FREE)

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 SEREVENT INHALER (CFC-FREE)?

SEREVENT INHALER (CFC-FREE) contains the active ingredient salmeterol xinafoate. SEREVENT INHALER (CFC-FREE) is used to keep the breathing tubes in your lungs open and relieves the symptoms of asthma and other chest conditions.

For more information, see Section <u>1. Why am I using SEREVENT INHALER (CFC-FREE)?</u> in the full CMI.

2. What should I know before I use SEREVENT INHALER (CFC-FREE)?

Do not use if you have ever had an allergic reaction to SEREVENT INHALER (CFC-FREE) 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 SEREVENT INHALER (CFC-FREE)? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SEREVENT INHALER (CFC-FREE) 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 SEREVENT INHALER (CFC-FREE)?

- For adults: the usual dose for asthma and COPD is two puffs twice daily. If you have asthma, your doctor may tell you to take four puffs twice daily if necessary
- For children 4 years or older: two puffs twice daily for asthma

More instructions can be found in Section 4. How do I use SEREVENT INHALER (CFC-FREE)? in the full CMI.

5. What should I know while using SEREVENT INHALER (CFC-FREE)?

Things you should do	 Remind any Healthcare Professional (HCP) you visit that you are using SEREVENT INHALER (CFC-FREE) Tell your doctor if you find your SEREVENT INHALER (CFC-FREE) does not help your breathing as much as usual Tell your doctor if you find your SEREVENT INHALER (CFC-FREE) does not last as long as usual 	
Things you should not do	 Do not stop using this medicine suddenly Do not use SEREVENT INHALER (CFC-FREE) to treat any other complaints unless your doctor says it is safe to do so Do not give SEREVENT INHALER (CFC-FREE) to anyone else, even though their symptoms may sound similar to yours 	
Driving or using machines	• Be careful driving or operating machinery until you know how SEREVENT INHALER (CFC-FREE) affects you.	
Looking after your medicine	 Store below 30°C Store in original packaging Do not store in the refrigerator 	

For more information, see Section 5. What should I know while using SEREVENT INHALER (CFC-FREE)? in the full CMI.

6. Are there any side effects?

Side effects which have been reported include tremor, headache, and muscle cramps.

Serious side effects include allergic reaction and heart palpitations.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

SEREVENT INHALER (CFC-FREE)

Active ingredient: salmeterol xinafoate

Consumer Medicine Information (CMI)

This leaflet provides important information about using SEREVENT INHALER (CFC-FREE). You should also speak to your Healthcare Professional (HCP) if you would like further information or if you have any concerns or questions about using SEREVENT INHALER (CFC-FREE).

Where to find information in this leaflet:

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

1. Why am I using SEREVENT INHALER (CFC-FREE)?

SEREVENT INHALER (CFC-FREE) contains the active

ingredient salmeterol xinafoate. SEREVENT INHALER (CFC-FREE) is a bronchodilator. It keeps the breathing tubes in your lungs open and relieves the symptoms of asthma and other chest conditions.

SEREVENT INHALER (CFC-FREE) is used to help you to breathe more easily. SEREVENT INHALER (CFC-FREE) gives relief, for up to twelve hours, from chest tightness or wheeze due to asthma, or other chest conditions in adults namely chronic obstructive pulmonary disease (COPD).

The medicine in SEREVENT INHALER (CFC-FREE) does not start working as quickly as a 'reliever' medicine such as VENTOLIN. SEREVENT INHALER (CFC-FREE) should not be used to relieve a sudden attack of breathlessness or wheezing. If you get this sort of attack, you must use a quick-acting inhaler (such as VENTOLIN/salbutamol).

2. What should I know before I use SEREVENT INHALER (CFC-FREE)?

Warnings

Do not use SEREVENT INHALER (CFC-FREE) if:

• you are allergic to salmeterol xinafoate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine

Check with your doctor if you:

- have any other medical conditions
 - thyroid conditions
 - heart conditions

- o diabetes
- o high blood pressure
- take any medicines for any other condition
- have had to stop taking other asthma medicines
- feel your asthma is not stable, or is getting worse

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. Are there any side effects</u>?

Pregnancy and breastfeeding

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

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

It is important that your asthma or chest condition is managed well during pregnancy and you should not stop your medicine without asking your doctor.

3. What if I am taking other medicines?

Tell your Healthcare Professional (HCP) 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. This should include all of the medicines that you are using for your asthma or COPD.

Some medicines may interfere with SEREVENT INHALER (CFC-FREE) 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 SEREVENT INHALER (CFC-FREE).

4. How do I take SEREVENT INHALER (CFC-FREE)?

How much to take

- for adults:
 - the usual dose for asthma and COPD is two puffs twice daily. If you have asthma, your doctor may tell you to take four puffs twice daily if necessary
- for children 4 years or older:
 - o two puffs twice daily for asthma
- follow the instructions provided and use SEREVENT INHALER (CFC-FREE) until your doctor tells you to stop

When to take SEREVENT INHALER (CFC-FREE)

 SEREVENT INHALER (CFC-FREE) should be used regularly every day, twice daily, in the morning and in the evening

How to use SEREVENT INHALER (CFC-FREE)

- straight after use, replace the mouthpiece cover firmly and click it into position. Do not use excessive force
- if you find it difficult to breathe in and use SEREVENT INHALER (CFC-FREE) at the same time, it may be better for you to use something called a 'spacer device' with your SEREVENT INHALER (CFC-FREE). Your doctor or pharmacist will explain to you what this is and how to use it
- if SEREVENT INHALER (CFC-FREE) becomes very cold, it may not work properly. To warm it, pull out the metal can from its plastic holder and warm it in your hand for a few minutes. Do not warm the can in any other way. Push the can firmly back into its holder before using
- you can estimate the number of doses left in your puffer by shaking it or by calculating approximately the number of doses that have been used
- floating the puffer in water to estimate the amount of doses left in the puffer is not recommended. Water may enter the valve in your puffer, which may affect the accuracy of later doses. The humidity from the water may also encourage bacteria to grow in the valve

You should always carry a spare puffer

If you forget to use SEREVENT INHALER (CFC-FREE)

SEREVENT INHALER (CFC-FREE) should be used regularly at the same time each day. If you miss your dose at the usual time, do not worry. Just take the next dose at the normal time.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

 if you become wheezy, or breathless, or develop any other symptoms of an asthma attack, use your quickacting inhaler (e.g. VENTOLIN/salbutamol), then seek medical advice.

If you use too much SEREVENT INHALER (CFC-FREE)

If you think that you have used too much SEREVENT INHALER (CFC-FREE), you may need urgent medical attention.

If you take more puffs by mistake, your heart may beat faster than usual, you may get a headache, you may experience muscle weakness and aching joints or you may feel shaky and tense.

You should immediately:

- phone the Poisons Information Centre (by calling 0800 POISON or 0800 764 766), 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 SEREVENT INHALER (CFC-FREE)?

Things you should do

If you have an asthma attack, use your 'reliever' medicine, not your SEREVENT INHALER (CFC-FREE).

Call your doctor straight away if you:

- find your SEREVENT INHALER (CFC-FREE) does not help your breathing as much as usual
- find your SEREVENT INHALER (CFC-FREE) does not last as long as usual

You will need to use a quick-acting inhaler medicine and tell your doctor as soon as possible. These may be signs that your asthma or chest condition is getting worse.

Remember, if you have asthma, you should also use your long-acting inhaler medicine (like an inhaled corticosteroid) regularly every day as your doctor has told you.

Remind any doctor, dentist or pharmacist you visit that you are using SEREVENT INHALER (CFC-FREE).

Things you should not do

- do not stop using this medicine suddenly
- do not use SEREVENT INHALER (CFC-FREE) to treat any other complaints unless your doctor says it is safe to do so
- do not give SEREVENT INHALER (CFC-FREE) to anyone else, even though their symptoms may sound similar to yours

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SEREVENT INHALER (CFC-FREE) affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- store below 30°C
- store in original packaging
- do not store in the refrigerator

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

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

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills

Keep it where young children cannot reach it.

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

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.

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

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
 Nervous system disorders: tremor headache Musculoskeletal and connective tissue disorders: muscle cramps joint pain 	Speak to your doctor if you have any of these less serious side effects and they worry you.
 Less serious side effects that require medical intervention. Please consult with your doctor if you experience any of the following: increase in blood sugar (hyperglycaemia). This may lead to increased thirst, frequent urination, or unexplained tiredness. 	Contact your doctor if you experience any of these less serious side effects.

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 via https://pophealth.my.site.com/carmreportnz/s/

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

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

What SEREVENT INHALER (CFC-FREE) contains

Active ingredient	salmeterol xinafoate
(main ingredient)	
Other ingredients	norflurane
(inactive ingredients)	

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

What SEREVENT INHALER (CFC-FREE) looks like

SEREVENT INHALER (CFC-FREE) is a green plastic holder which contains a small metal can. The holder has a mouthpiece which is covered by a light green cap. The holder has "Serevent Inhaler" written on it (TT50-4568/5).

Who distributes SEREVENT INHALER (CFC-FREE)

GlaxoSmithKline NZ Ltd Private Bag 106600 Downtown Auckland 1143

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