SEREVENT ACCUHALER

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 ACCUHALER?

SEREVENT ACCUHALER contains the active ingredient salmeterol xinafoate. SEREVENT ACCUHALER 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</u> <u>SEREVENT ACCUHALER?</u> in the full CMI.

2. What should I know before I use SEREVENT ACCUHALER?

Do not use if you have ever had an allergic reaction to SEREVENT ACCUHALER 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</u> <u>before I use SEREVENT ACCUHALER?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SEREVENT ACCUHALER and affect how it works.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I use SEREVENT ACCUHALER?

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

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

5. What should I know while using SEREVENT ACCUHALER?

Things you should do	 Remind any Healthcare Professional (HCP) you visit that you are using SEREVENT ACCUHALER Tell your doctor if you find your SEREVENT ACCUHALER does not help your breathing as much as usual Tell your doctor if you find your SEREVENT ACCUHALER does not last as long as usual
Things you should not do	 Do not stop using this medicine suddenly Do not use SEREVENT ACCUHALER to treat any other complaints unless your doctor says it is safe to do so Do not give SEREVENT ACCUHALER 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 ACCUHALER affects you.
Looking after your medicine	 Store below 30°C Store in original packaging

For more information, see Section <u>5. What should I know</u> while using SEREVENT ACCUHALER? 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</u> <u>effects?</u> in the full CMI.

SEREVENT ACCUHALER

Active ingredient: salmeterol xinafoate

Consumer Medicine Information (CMI)

This leaflet provides important information about using SEREVENT ACCUHALER. 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 ACCUHALER.

Where to find information in this leaflet:

1. Why am I using SEREVENT ACCUHALER?

2. What should I know before I use SEREVENT ACCUHALER?

- 3. What if I am taking other medicines?
- 4. How do I use SEREVENT ACCUHALER?

5. What should I know while using SEREVENT ACCUHALER?

6. Are there any side effects?

7. Product details

1. Why am I using SEREVENT ACCUHALER?

SEREVENT ACCUHALER contains the active ingredient salmeterol xinafoate. SEREVENT ACCUHALER is a bronchodilator. It keeps the breathing tubes in your lungs open and relieves the symptoms of asthma and other chest conditions.

SEREVENT ACCUHALER is used to help you to breathe more easily. SEREVENT ACCUHALER 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 ACCUHALER does not start working as quickly as a 'reliever' medicine such as VENTOLIN/salbutamol. SEREVENT ACCUHALER 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 ACCUHALER?

Warnings

Do not use SEREVENT ACCUHALER 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
- diabetes
- high blood pressure
- take any medicines for any other condition
- have been diagnosed with an intolerance to some sugars, or to milk protein
- 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 ACCUHALER 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 ACCUHALER.

4. How do I take SEREVENT ACCUHALER?

How much to take

- for adults:
 - the usual dose for asthma and COPD is one blister twice daily. If you have asthma, your doctor may tell you to take two blisters twice daily if necessary
- for children 4 years or older:
 one blister twice daily for asthma
- follow the instructions provided and use SEREVENT ACCUHALER until your doctor tells you to stop

When to take SEREVENT ACCUHALER

 SEREVENT ACCUHALER should be used regularly every day, twice daily, in the morning and in the evening

How to use SEREVENT ACCUHALER

• SEREVENT ACCUHALER has a dose counter which tells you how many doses are left. When you have reached the last five doses, the numbers appear in red

If you forget to use SEREVENT ACCUHALER

SEREVENT ACCUHALER 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 ACCUHALER

If you think that you have used too much SEREVENT ACCUHALER, you may need urgent medical attention.

If you take more blisters by mistake, your heart may beat faster than usual, you may get a headache, or you may feel shaky and tense.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia), 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 ACCUHALER?

Things you should do

If you have an asthma attack, use your 'reliever' medicine, not your SEREVENT ACCUHALER.

Call your doctor straight away if you:

- find your SEREVENT ACCUHALER does not help your breathing as much as usual
- find your SEREVENT ACCUHALER 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 ACCUHALER.

Please see Section <u>6. Are there any side effects</u>? For more instances in which you should contact your doctor.

Things you should not do

- do not stop using this medicine suddenly
- do not use SEREVENT ACCUHALER to treat any other complaints unless your doctor says it is safe to do so
- do not give SEREVENT ACCUHALER 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 ACCUHALER affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- store below 30°C
- store in original packaging

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

Serious side effects

Serious side effects	What to do
Immune system disorders and allergic reactions:	Call your doctor straight away, or go straight to the Emergency
 Symptoms of an allergic reaction usually include some or all of the following: shortness of breath wheezing, coughing or difficulty breathing swelling of the face, lips, tongue or other parts of the body (angioedema) rash, itching, redness or hives on the skin (urticaria) suddenly feeling weak or light headed (may lead to collapse or loss of consciousness) Cardiac disorders: palpitations irregular or fast 	Department at your nearest hospital if you notice any of these serious side effects.
heartbeat	

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 <u>www.tga.gov.au/reporting-problems</u>. 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 ACCUHALER contains

Active ingredient (main ingredient)	salmeterol xinafoate
Other ingredients	lactose monohydrate
(inactive ingredients)	(contains milk protein)

Each blister (dose) contains 50 micrograms of the active ingredient salmeterol xinafoate.

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

What SEREVENT ACCUHALER looks like

SEREVENT ACCUHALER is a green-coloured plastic device which contains a foil strip inside. The foil strip has 28 or 60 blisters (or pockets) which contain your medicine (AUST R 53775).

Who distributes SEREVENT ACCUHALER

GlaxoSmithKline Australia Pty Ltd

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www.gsk.com.au

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