

PATIENT INFORMATION LEAFLET FOR
ASTHAVENT ECOHALER

Scheduling Status:

S2

ASTHAVENT ECOHALER (100 µg Metered dose inhaler)

Salbutamol sulphate

Read all of this leaflet carefully because it contains important information for you.

ASTHAVENT ECOHALER is available without a doctor's prescription. Nevertheless, you still need to use ASTHAVENT ECOHALER carefully to get the best results from it.

- Keep this leaflet, you may need to read it again.
- Do not share ASTHAVENT ECOHALER with any other person.
- Ask your pharmacist or doctor if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after using ASTHAVENT ECOHALER, or if the recommended dosage is effective for less than 3 hours.

What is in this leaflet

1. What ASTHAVENT ECOHALER is and what it is used for
2. What you need to know before you use ASTHAVENT ECOHALER
3. How to use ASTHAVENT ECOHALER
4. Possible side effects
5. How to store ASTHAVENT ECOHALER
6. Contents of the pack and other information.

1. What ASTHAVENT ECOHALER is and what it is used for

ASTHAVENT ECOHALER contains salbutamol sulphate equivalent to salbutamol, which is one of a group of medicines called fast acting bronchodilators.

Salbutamol relaxes the muscles in the walls of the air passages in the lungs. This helps to open up the airways and helps to relieve chest tightness, wheezing and cough, so you can breathe more easily.

ASTHAVENT ECOHALER is used to ease breathing problems in asthma and other chest illnesses. ASTHAVENT ECOHALER can also be used to avoid getting worse in breathing problems in asthma and other chest illnesses.

ASTHAVENT ECOHALER is used to treat and prevent reversible constriction of the airways (bronchospasm) due to bronchial asthma, chronic bronchitis, and emphysema.

2. What you need to know before you use ASTHAVENT ECOHALER

Do not use ASTHAVENT ECOHALER

- If you are allergic (hypersensitive) to salbutamol, or any of the other components of ASTHAVENT ECOHALER (listed in **Section 6**).
- If you are taking propranolol, sotalol, timolol or other beta-blockers for heart disorders, high blood pressure or glaucoma, as these medicines counteract the effects of ASTHAVENT ECOHALER and should not be taken concurrently (see **‘Other medicines and ASTHAVENT ECOHALER’**).
- If you are taking mono-amine oxidase inhibitors, including selegiline for Parkinson’s disease or moclobemide for depression, or within 14 days after stopping such medicines. Please ask your doctor or pharmacist for advice (see **‘Other medicines and ASTHAVENT ECOHALER’**).

- If you are pregnant or breastfeeding your baby, as safety has not been established (see '**Pregnancy, breastfeeding and fertility**').
- If you unexpectedly go into early labour (premature labour) or threatened abortion.

Warnings and Precautions

Take special care with ASTHAVENT ECOHALER if:

- Your difficult breathing persists or if your condition worsens.
- You require more ASTHAVENT ECOHALER inhalations than usual to relieve an acute attack.
- You suddenly find it increasingly difficult to breathe, or if you suddenly develop severe wheezing after using ASTHAVENT ECOHALER (see '**Possible Side Effects**'). Stop using ASTHAVENT ECOHALER immediately and consult your doctor.

Failure to respond promptly or fully to ASTHAVENT ECOHALER shows that you require urgent medical attention.

If you have diabetes, as ASTHAVENT ECOHALER may cause an increase in the amount of glucose (sugar) in your blood.

Do NOT use more ASTHAVENT ECOHALER than recommended (see '**How to use ASTHAVENT ECOHALER**'). Excessive use of ASTHAVENT ECOHALER may lead to life-threatening irregular heart rhythms or heart arrest.

If you have been diagnosed with heart disease, you need to discuss the use of ASTHAVENT ECOHALER with your doctor or pharmacist. If you are known with heart disease, abnormal heart rhythm, high blood pressure, heart failure, or previously had a heart attack or required a cardiac bypass operation or stent, you must inform your doctor

immediately if you develop chest pain, palpitations, or swelling of the feet or ankles.

If you have been diagnosed with an overactive thyroid gland, please discuss the use of ASTHAVENT ECOHALER with your doctor.

If you find that you have to use increasing amounts of ASTHAVENT ECOHALER to control your breathing, you should not simply increase the use of ASTHAVENT ECOHALER beyond the recommended dose, as this may be dangerous to your health (see '**How to use ASTHAVENT ECOHALER**'). This may indicate that your asthma is deteriorating or not under control and you must consult your doctor, as your current treatment plan may need to be reassessed. Worsening of your asthma control may be life-threatening and your doctor may need to start, or increase your dose of, corticosteroids (steroids).

If a previously effective dose of ASTHAVENT ECOHALER fails to provide relief for at least 3 hours, you should seek medical advice, as you may require a change in your treatment plan (see '**How to use ASTHAVENT ECOHALER**').

If you need help with using the inhaler correctly, please ask your doctor or pharmacist for help.

ASTHAVENT ECOHALER may cause a fine tremor of your hands or other muscles (see '**Possible Side Effects**'). If this side effect should continue or become bothersome, please discuss the continued use of ASTHAVENT ECOHALER with your doctor.

Use of ASTHAVENT ECOHALER may lower your blood potassium levels, which may result in palpitations (see '**Possible Side Effects**'). If you suffer from severe asthma, are taking theophylline, steroids, or water tablets (diuretics) (see '**Other medicines and**

ASTHAVENT ECOHALER'), your doctor may have to do blood tests to check your potassium levels.

Older people may be more sensitive to the side effects of **ASTHAVENT ECOHALER** (see '**Possible Side Effects**').

Other medicines and ASTHAVENT ECOHALER

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are currently taking any of the following medicines, please ask your doctor or pharmacist for advice before you start using **ASTHAVENT ECOHALER**:

- Propranolol, sotalol, timolol or other beta-blockers for heart disorders, high blood pressure or glaucoma. These medicines may block the effect of **ASTHAVENT ECOHALER** (see '**Do not use ASTHAVENT ECOHALER**') or cause your airways to constrict.
- Theophylline (and other xanthine derivatives) to open up the airways, fluticasone, budesonide, or other steroids for asthma or other conditions, or water tablets (diuretics), e.g. hydrochlorothiazide or furosemide. Combination of these medicines with **ASTHAVENT ECOHALER** may lower your blood potassium levels, which in turn may give rise to abnormal heart rhythms (see '**Warnings and Precautions**').
- Digoxin or quinidine for heart failure or abnormal heart rhythms, or tricyclic antidepressants (e.g. amitriptyline, clomipramine or imipramine), since combination of these medicines with **ASTHAVENT ECOHALER** may increase your risk of developing an irregular heart rhythm.

- Other medicines or substances known to increase blood pressure or heart rate (such as ephedrine/adrenaline), pseudoephedrine in cold and flu preparations, methylphenidate for attention deficit hyperactivity disorder (ADHD), or cocaine or other recreational drugs.

If you are scheduled to undergo surgery, remember to inform your doctor or anaesthetist that you are using ASTHAVENT ECOHALER.

If you are also using other inhalation medicines for the treatment of asthma or tightness of the chest (e.g. steroid or ipratropium inhalations), use ASTHAVENT ECOHALER 5 minutes before your other medicine(s), unless otherwise directed by your doctor.

Pregnancy, breastfeeding and fertility

Do not use ASTHAVENT ECOHALER if you are pregnant or breastfeeding your baby, as safety has not been established (see **‘What you need to know before you use ASTHAVENT ECOHALER’**).

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ASTHAVENT ECOHALER.

Driving and using machines

ASTHAVENT ECOHALER is unlikely to affect your ability to drive or operate machinery.

3. How to use ASTHAVENT ECOHALER

Do not share your medicine with any other person.

Always use ASTHAVENT ECOHALER exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if

you are unsure.

Your doctor will tell you how long your treatment with ASTHAVENT ECOHALER will last.

If you have the impression that the effect of ASTHAVENT ECOHALER is too strong or too weak, tell your doctor or pharmacist.

ASTHAVENT ECOHALER produces a fine mist which you must inhale into your lungs. Make sure that you know how to use the inhaler properly. The instructions are given later on in this leaflet. If you have any problems ask your doctor, nurse or pharmacist. ASTHAVENT ECOHALER must be breathed in through the mouth.

Use one or two inhalations, repeated four-hourly if required. The bronchodilator effect of each administration of ASTHAVENT ECOHALER lasts for at least four hours and more frequent use should be unnecessary.

You must not inhale more puffs, or use your inhaler more often, than the doctor told you to.

Your doctor may have told you to take more than this as an emergency treatment if your wheezing or breathing gets very bad. It is very important that you keep to your doctor's instructions as to how many puffs to take and how often to use your inhaler.

After using your ASTHAVENT ECOHALER

- If your breathing or wheezing gets worse straight after using ASTHAVENT ECOHALER, stop using it immediately and tell your doctor as soon as possible.
- If the relief of wheezing or chest tightness is not as good as usual or does not

last for as long as usual, tell your doctor as soon as possible. Your chest condition may be getting worse and you may need an extra medicine.

- If you need to use your ASTHAVENT ECOHALER much more often than normal, see your doctor as soon as possible.

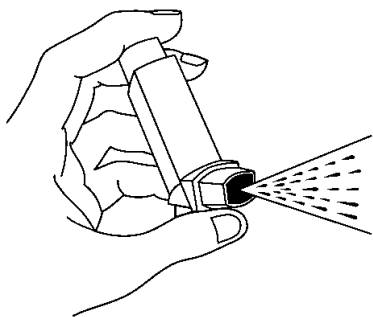
How to use ASTHAVENT ECOHALER correctly:

Important

Follow instructions carefully.

Before using ASTHAVENT ECOHALER for the first time

1. Remove the cap / cover from the mouthpiece and ensure that the mouthpiece is clean.
2. Hold the inhaler away from your face. Shake it well and release two puffs into the air.



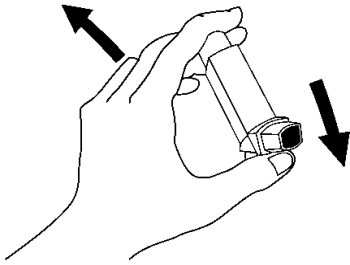
3. Your ASTHAVENT ECOHALER is now ready for use.

If your inhaler has not been used for a week or more, shake it well and release one puff into the air.

Using ASTHAVENT ECOHALER

1. Sit or stand upright. Remove the mouthpiece cap / cover and shake ASTHAVENT ECOHALER well. Hold it upright as shown, with the thumb at the

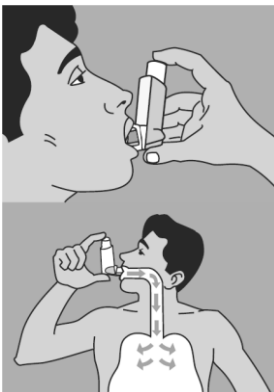
base below the mouthpiece. Place either one or two fingers on top of the canister.



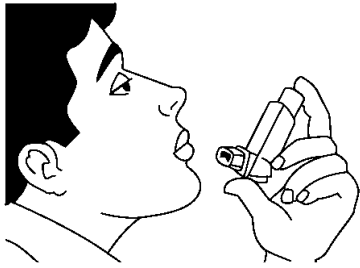
2. **Breathe out fully**, through your mouth.



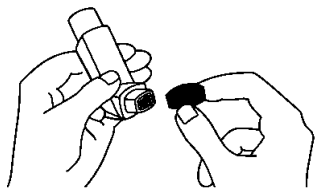
3. Place the mouthpiece of the inhaler in your mouth between your teeth and close your lips around it (do not bite it). **Start to breathe in slowly through your mouth. Press the canister down firmly and fully to release one spray while you continue to breathe in slowly and deeply.**



4. Remove the ASTHAVENT ECOHALER from your mouth and hold your breath for at least 10 seconds, or as long as it is comfortable. Breathe out normally.

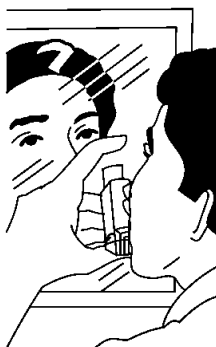


5. If another dose is required, wait for at least one minute. Shake ASTHAVENT ECOHALER well and repeat steps 2 to 4. After use, replace the mouthpiece cap / cover firmly and snap it into position.

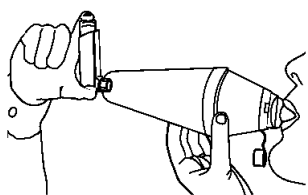


NOTE

Do not rush stages 2, 3 and 4. It is important to breathe in slowly through your mouth, just before pressing the canister. To ensure proper use of ASTHAVENT ECOHALER, you may initially practice these steps in front of a mirror until you are comfortable with the technique. If there is 'mist' escaping from the inhaler or the sides of your mouth, start again from step 1. This escaping mist indicates incorrect technique.

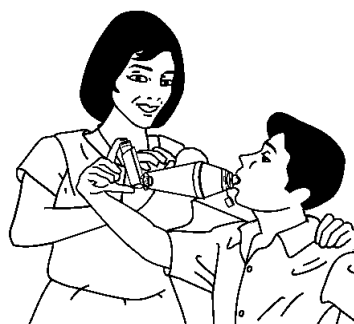


If you find it difficult to use the device correctly, you may use a spacer device along with ASTHAVENT ECOHALER.

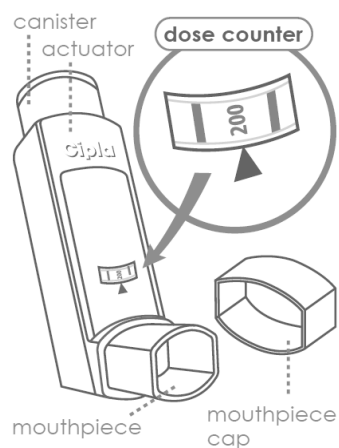


For children

Parents must assist those children who need help in using the ASTHAVENT ECOHALER correctly with/without a spacer.



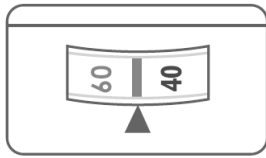
Dose counters



ASTHAVENT ECOHALER containing 200 doses has a dose counter. It shows the number of puffs in the inhaler. As you use the inhaler, the dose counter will countdown and indicate the number of remaining puffs.

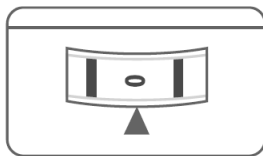
How to know that your ASTHAVENT ECOHALER is nearly empty

When there are 40 puffs remaining, the colour of the numbers will change from green to red.



This indicates that there are 40 or fewer puffs left in the ASTHAVENT ECOHALER. You should now consider getting a new ASTHAVENT ECOHALER, or asking your doctor whether you need another one.

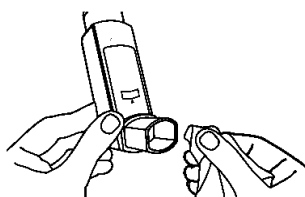
When the dose counter displays '0', it means that there is no medicine left in the ASTHAVENT ECOHALER and you need to discard it. Your ASTHAVENT ECOHALER may not feel empty and it may continue to operate, but you will not receive the correct amount of medicine if you keep using this canister.



Cleaning your ASTHAVENT ECOHALER

It is important to keep your ASTHAVENT ECOHALER clean. Clean your ASTHAVENT ECOHALER at least once a week.

1. Remove the mouthpiece cap / cover. **DO NOT take the metal canister out of the actuator.**
2. Wipe the inside and the outside of the mouthpiece with a clean, dry cloth.
3. Replace the mouthpiece cap / cover.
4. **DO NOT wash or soak any part of ASTHAVENT ECOHALER in water.**



DO NOT

- Spray ASTHAVENT ECOHALER in your eyes.
- Exceed the recommended dose.
- Change / tamper with the numbers on the dose counter.
- Puncture or burn your ASTHAVENT ECOHALER even when empty, as it is pressurised.

If you use more ASTHAVENT ECOHALER than you should

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

If you use more ASTHAVENT ECOHALER than you should, you may develop a rapid heart rate, tremor, hyperactivity and electrolyte imbalances including lowering of your blood potassium levels that may cause abnormal heart rhythms (see '**Possible Side Effects**').

If you forget to use ASTHAVENT ECOHALER

Always use ASTHAVENT ECOHALER as directed. If you miss a dose, use ASTHAVENT ECOHALER as soon as possible. However, if you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose to make up for the forgotten individual dose.

4. Possible Side Effects

ASTHAVENT ECOHALER can have side effects.

Not all side effects reported for ASTHAVENT ECOHALER are included in this leaflet.

Should your general health worsen while using ASTHAVENT ECOHALER, please

consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking ASTHAVENT ECOHALER and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions, including swelling of the tongue, lips or face, hives, swelling of the throat with difficult breathing, low blood pressure, or collapse.
- Unexpected constriction of the airways with wheezing or tightness of the chest (see **‘Warnings and Precautions’**).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ASTHAVENT ECOHALER. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain, especially pain that goes up to the chin or down the left arm (see **‘Warnings and Precautions’**).
- Shortness of breath.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Hyperactivity in children.
- Tremors (see **‘Warnings and Precautions’**), headache.
- Rapid heart rate.

Less frequent side effects:

- Palpitations or irregular heart beat (see **‘Warnings and Precautions’**).

- Redness of the feet, legs or hands due to dilation of blood vessels.
- Dryness and irritation of your mouth or throat (see '**How to use ASTHAVENT ECOHALER**').
- Muscle cramps.

Side effects with unknown frequency:

- Confusion.
- Struggling to pass urine or inability to pass urine.
- Altered metabolism, reduced appetite, sweating.
- Nervousness, fear, sleeplessness, tenseness.
- Dizziness, light-headedness.
- Coughing.
- Increased salivation, nausea and vomiting.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafety@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ASTHAVENT ECOHALER.

5. How to store ASTHAVENT ECOHALER

Store at or below 25 °C and protected from direct sunlight. Do not freeze. Do not

puncture, break or burn, even when apparently empty.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

6. Contents of the pack and other information

What ASTHAVENT ECOHALER contains

The active ingredient is salbutamol sulphate 100 µg.

Propellant 134a (tetrafluoroethane).

What ASTHAVENT ECOHALER looks like and contents of the pack

ASTHAVENT ECOHALER: A white, homogenous suspension aerosol for inhalation, in propellant HFA-134a, supplied in an aluminium pressurised container fitted with a metered dispensing valve attached to a mouthpiece.

ASTHAVENT ECOHALER is packed in a carton containing a metered dose inhaler with 200 or 300 doses of salbutamol 100 µg each, supplied in an aluminium pressurised container with 'SHAKE WELL BEFORE USE" embossed on the base, fitted with a metered dispensing valve attached to a mouthpiece.

The 200 MD ASTHAVENT ECOHALER is available with or without a dose counter.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:
The QR Code to
be generated and
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approval.