

**PACKAGE INSERT FOR**  
**ASTHAVENT ECOHALER**

**SCHEDULING STATUS:**

**S2**

**PROPRIETARY NAME** (AND DOSAGE FORM):

**ASTHAVENT ECOHALER** (Metered dose inhaler)

**COMPOSITION:**

Each actuation contains salbutamol sulphate equivalent to salbutamol 100 µg.

Non-CFC formulation.

The inactive ingredient is tetrafluoroethane (also known as HFA-134a).

**PHARMACOLOGICAL CLASSIFICATION:**

A 10.2.1 Bronchodilators (inhalants).

**PHARMACOLOGICAL ACTION:**

Salbutamol is a direct-acting sympathomimetic agent, a selective  $\beta_2$ -adrenergic agonist that activates the pulmonary receptors to relax the bronchial smooth muscle and decrease airway resistance. Evidence suggests that salbutamol may inhibit the release of leukotrienes and histamines from the mast cells in the pulmonary tissue, that it may enhance mucociliary function, decrease microvascular permeability and inhibit phospholipase A<sub>2</sub>.

### **Pharmacokinetics:**

Bronchodilation is produced within 5 to 15 minutes after inhalation, with therapeutic effects lasting for 4 to 6 hours. In therapeutic doses, salbutamol has minimal effect on the cardiovascular system.

The systemic absorption of inhaled salbutamol is low and it has been suggested that the majority of an inhaled dose is swallowed and absorbed from the gastro-intestinal tract and excreted in the urine.

The therapeutic effect of inhaled salbutamol is dependent on direct stimulation of receptors in the lungs.

### **INDICATIONS:**

**ASTHAVENT ECOHALER** is indicated:

- For the treatment and prophylaxis of reversible airways obstruction associated with bronchial asthma, chronic bronchitis and emphysema.
- For the prevention of exercise-induced bronchospasm.

### **CONTRAINDICATIONS:**

- Hypersensitivity to salbutamol.
- Propranolol and other beta-adrenoceptor blocking agents antagonise the effects of **ASTHAVENT ECOHALER** and should not be prescribed together.
- Sympathomimetic agents should not be prescribed to patients receiving monoamine oxidase inhibitors or within 14 days after termination of such therapy.
- Safety in pregnancy and lactation has not been established.

## **WARNINGS AND SPECIAL PRECAUTIONS:**

If difficulty in breathing persists, or if the condition deteriorates, or if more inhalations than usual are needed to relieve an acute attack, a medical practitioner should be consulted immediately.

Hypokalaemia may occur (see "**INTERACTIONS**" and "**Side-Effects**").

Overdosage may cause cardiac effects.

High doses may increase the risk of serious side-effects, including cardiac dysrhythmias. This risk is further aggravated if **ASTHAVENT ECOHALER** is administered concomitantly with other medicines that cause hypokalaemia and cardiac dysrhythmias, or in the presence of hypoxia and acidosis. The maximum dose should not be exceeded.

The excessive use of inhaled sympathomimetic medication may lead to life-threatening cardiac arrest following the development of severe acute crisis and subsequent hypoxia. **It is important to avoid the excessive use of ASTHAVENT ECOHALER.**

Caution is advised when **ASTHAVENT ECOHALER** is prescribed to patients suffering from thyrotoxicosis.

**ASTHAVENT ECOHALER** should be given with caution to patients suffering from cardiac dysrhythmias, coronary insufficiency, hypertension or ischaemic heart disease, diabetes mellitus, and susceptibility to QT-interval prolongation.

### **INTERACTIONS:**

Extreme caution is advised when beta-adrenergic blocking agents, such as propranolol, are prescribed to patients using **ASTHAVENT ECOHALER**, as beta-blockage may antagonise the bronchodilatory effect of salbutamol, and may in fact induce bronchospasm.

The concomitant use of xanthine derivatives, steroids and diuretics may potentiate the possible hypokalaemic effect of **ASTHAVENT ECOHALER** in patients suffering from acute severe asthma. The risk of hypokalaemia may be increased in the presence of hypoxia and acidosis (see "**WARNINGS AND SPECIAL PRECAUTIONS**"). Serum potassium levels should be monitored in such situations.

**ASTHAVENT ECOHALER** should be used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics. The concurrent use of these medicines may cause ventricular fibrillation.

The risk of dysrhythmias may be increased with the concurrent use of cardiac glycosides, quinidine and tricyclic antidepressants.

Caution is advised when **ASTHAVENT ECOHALER** is prescribed to patients who have received large doses of other sympathomimetic agents.

**ASTHAVENT ECOHALER** should be used 5 minutes prior to the administration of adrenocorticoid or ipratropium inhalations, unless otherwise directed by a physician.

Older patients may be more sensitive to the side-effects of **ASTHAVENT ECOHALER**.

**DOSAGE AND DIRECTIONS FOR USE:**

FOR ORAL INHALATION ONLY. SHAKE WELL BEFORE USE.

Read the instructions carefully.

Avoid contact with the eyes.

Do not exceed the recommended dose. The frequency and the dosage should only be increased if so advised by a medical practitioner.

Rinse the mouth with water after each inhalation to help prevent dryness of the mouth and throat.

**Adults:**

Acute bronchospasm: 1 or 2 inhalations (100 – 200 µg salbutamol) as a single dose.

Chronic bronchospasm: 1 or 2 inhalations (100 – 200 µg salbutamol) 3 – 4 times daily.

Exercise-induced bronchospasm: 2 inhalations (200 µg salbutamol) 15 minutes before exercise.

**Warning:**

If more than one inhalation is needed per day, it is recommended that additional treatment with an inhaled corticosteroid be considered.

Consult a doctor if a previous inhalation is effective for less than 3 hours.

**Children (over 12 years):**

Acute bronchospasm: 1 inhalation (100 µg salbutamol) as a single dose.

Episodic or exercise-induced asthma: 1 inhalation (100 µg salbutamol) 15 minutes before exercise.

Chronic maintenance or prophylaxis: 1 inhalation (100 µg salbutamol) 3 or 4 times daily.

Increase to 2 inhalations (200 µg salbutamol) 3 or 4 times daily if necessary.

**SIDE-EFFECTS:**

Fine tremor of the skeletal muscles may occur, particularly of the hands.

Palpitations and muscle cramps may occur.

After large doses, tachycardia, headache, tenseness and peripheral vasodilation have been reported.

Hypokalaemia may occur, but the incidence is less frequent (see "**INTERACTIONS**" and "**WARNINGS AND SPECIAL PRECAUTIONS**").

Paradoxical or hypersensitivity-induced bronchospasm may occur. Should this happen, it is advised that therapy with **ASTHAVENT ECOHALER** be discontinued immediately and alternative treatment instituted. Hypersensitivity reactions may also include angioedema, urticaria, hypotension, and collapse.

Coughing and dryness or irritation of the mouth or throat have been reported.

Nausea and vomiting have been reported.

Central nervous system effects may occur, and may include nervousness, dizziness, confusion, fear, insomnia and light-headedness.

Appetite may be reduced.

Difficulty in micturition, urinary retention, sweating, hypersalivation, altered metabolism and dyspnoea may occur.

## **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS**

### **TREATMENT:**

The cardiovascular and skeletal muscle side-effects may be more pronounced. See "**SIDE-EFFECTS**".

A cardioselective beta-blocking agent should be administered with caution, especially in patients with a history of bronchospasm.

### **IDENTIFICATION:**

Milky-white homogenous suspension in non-CFC propellant filled in an aluminium pressurised container.

**PRESENTATION:**

Metered dose inhaler containing 200 or 300 doses of salbutamol 100 µg each, presented in an aluminium canister with a metered dispensing valve, attached to a mouthpiece with cover.

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

**STORAGE INSTRUCTIONS:**

Store in well-closed containers at or below 25 °C, protected from direct sunlight. Do not freeze. Do not puncture, break or burn, even when apparently empty.

**KEEP OUT OF REACH OF CHILDREN.**

**REGISTRATION NUMBER:**

34/10.2.1/0354

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF**

**REGISTRATION:**

CIPLA MEDPRO (PTY) LTD

Building 9

Parc du Cap

Mispel Street

Bellville

7530



RSA

Customer care: 080 222 6662

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

April 2005

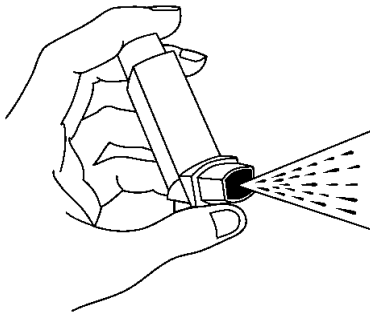
**For 200 and 300 metered dose ASTHAVENT ECOHALER with no dose counter:**

**HOW TO USE YOUR ECOHALER CORRECTLY:**

**Important:** Follow instructions carefully.

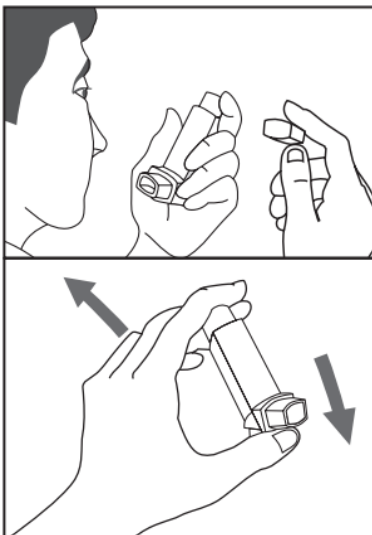
**Testing your Ecohaler:**

Before using the **Ecohaler** for the first time, or if it has not been used for a week or more, 'test fire' it, i.e. release two puffs into the air away from face.



**Instructions for correct use**

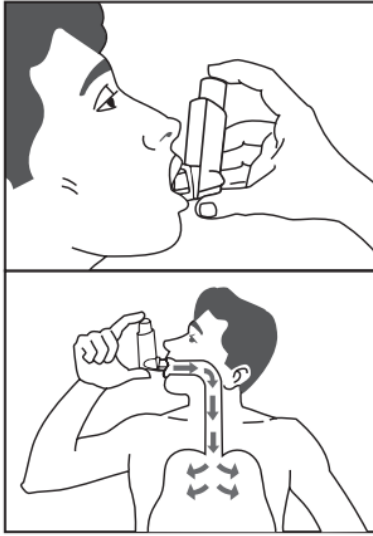
1. Remove the mouthpiece cover and check the mouthpiece thoroughly to see that it is clean. Shake the **Ecohaler** well before use.



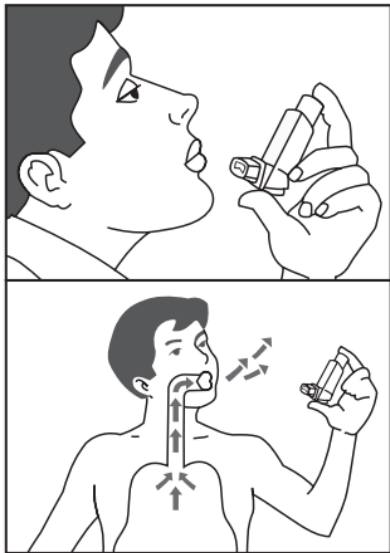
2. Hold the **Ecohaler** as shown between index finger and thumb. Alternatively, hold the inhaler with both hands. Breathe out gently through your mouth and immediately place the mouthpiece in your mouth between your teeth (do not bite it).



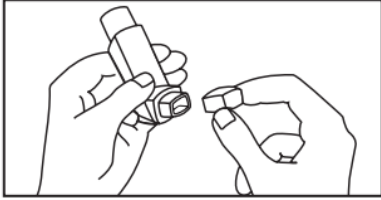
3. Grip the mouthpiece firmly with your lips. Tilt your head slightly backwards. Start breathing in slowly through your mouth. At the same time press the canister as shown, to release one dose while continuing to breathe in steadily and deeply.



4. Remove the **Ecohaler** from your mouth. Hold your breath for at least 10 seconds, or as long as it is comfortable. Breathe out slowly.



5. If another dose is required, wait for at least one minute. Repeat steps 2 to 4. After use, replace the mouthpiece cover.



## NOTE

Do not rush stages 2 and 3. It is important to breathe in slowly through your mouth, just before pressing the canister. To ensure proper use of your **Ecohaler**, you may initially practice these steps in front of a mirror until you are comfortable with the technique.

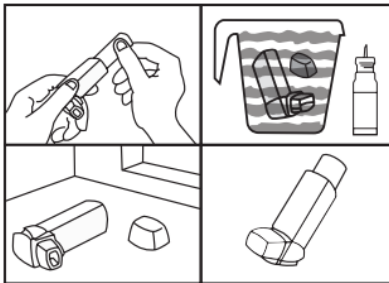


## For children

Young children may need help. To help the child, parents must first learn the technique correctly themselves, then properly guide the child to use the **Ecohaler**.



## Cleaning



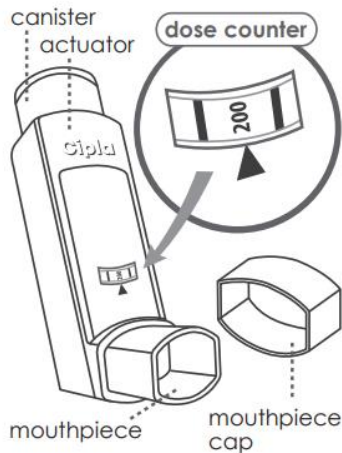
Clean your **Ecohaler** at least once a week.

1. Gently pull the canister out of the adapter of the **Ecohaler**. Remove the mouthpiece cover.
2. Rinse the adapter and the mouthpiece cover in warm water, but do not put the metal canister into the water.
3. Leave to dry in a warm place. Avoid excessive heat.
4. Replace the canister and the mouthpiece cover correctly. Make sure the canister is fully inserted into the actuator.

**For 200 metered dose ASTHAVENT ECOHALER with a dose counter:**

**ABOUT YOUR ASTHAVENT ECOHALER**

**PARTS OF THE ECOHALER**

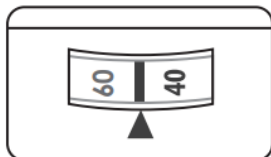


**DOSE COUNTERS**

**ASTHAVENT EcoHaler** containing 200 doses now come with a dose counter. It shows the number of puffs in the **EcoHaler**. As you use the **EcoHaler**, the dose counter will countdown and indicate the number of puffs remaining.

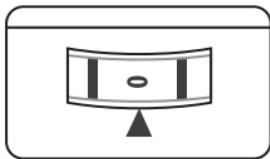
**HOW TO KNOW THAT YOUR ASTHAVENT ECOHALER IS NEARLY EMPTY**

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 **EcoHaler**. You should now consider getting a new **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 **EcoHaler** & you need to discard it. Your **EcoHaler** may not feel empty & it may continue to operate, but you will not receive the correct amount of medicine if you keep using this canister.



### **How to use your EcoHaler correctly:**

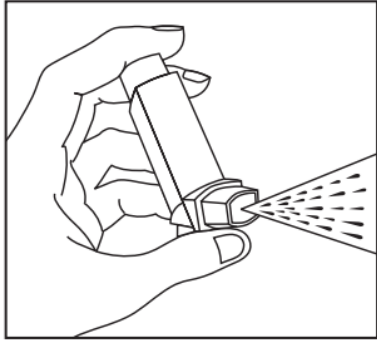
#### **Important:**

Follow instructions carefully.

#### **Before using your EcoHaler for the first time:**

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

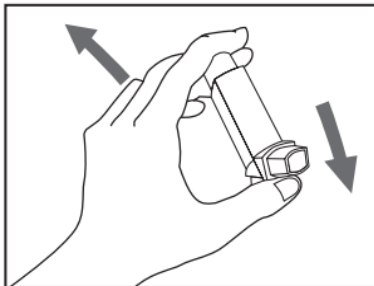




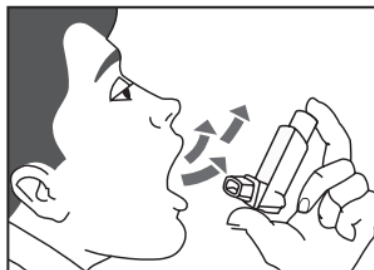
3. Your **EcoHaler** is now ready for use. **If you have not used your EcoHaler for a week or more, shake well and release one puff into the air.**

#### **Using your EcoHaler:**

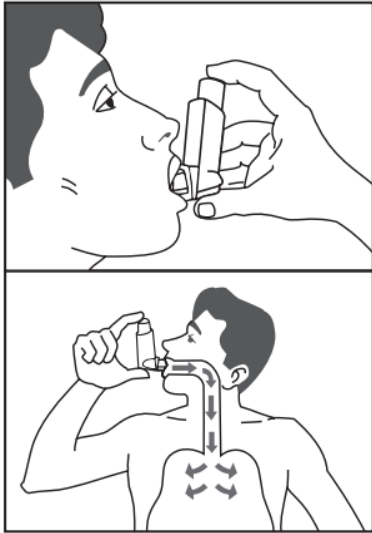
1. Sit or stand upright. Remove the mouthpiece cap/cover and shake the **EcoHaler** well. Hold it upright as shown, with your thumb at the base below the mouthpiece. Place either one or two fingers on top of the canister.



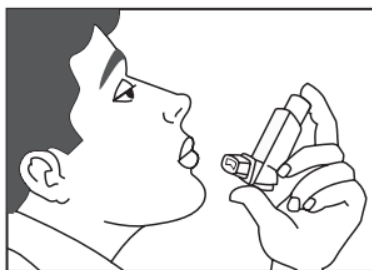
2. **Breathe out fully**, through your mouth.



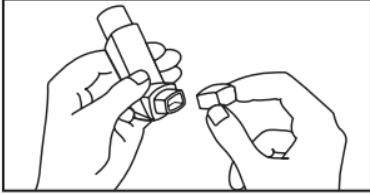
3. Place the mouthpiece of the **EcoHaler** in your mouth between your teeth and close your lips around it (do not bite it). **Start breathing in slowly through your mouth. Press the canister down firmly and fully to release one spray while continuing to breathe in slowly and deeply.**



4. Remove the **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 the **EcoHaler** well and repeat steps 2 to 4. After use, replace the mouthpiece cap/cover firmly and snap it into position.

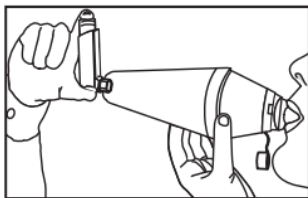


**NOTE:**

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 your **EcoHaler**, you may initially practice these steps in front of a mirror until you are comfortable with the technique. If you see mist escaping from the **EcoHaler** 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 the EcoHaler.**



**For children:**

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



### **Cleaning your EcoHaler:**

It is essential to clean the actuator, to avoid it from blocking.

Clean your inhaler at least once a week, as follows:

- 1) Gently pull out the metal canister from the actuator of the inhaler. Remove the mouthpiece cap from the actuator.
- 2) Immerse the actuator and the mouthpiece cap in warm water. Do not put the metal canister in water.
- 3) Next, rinse the actuator and the mouthpiece cap thoroughly under running tap water.
- 4) Shake well to remove excess water.
- 5) Leave to air-dry. Avoid excessive heat.

6) When the actuator is dry, replace the metal canister into the actuator so that it fits firmly and then replace the mouthpiece cap.

**DO NOT:**

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