

PATIENT INFORMATION LEAFLET FOR
ASTHAVENT SYRUP

Scheduling Status

S2

ASTHAVENT SYRUP 2 mg/5 mL

Salbutamol as salbutamol sulphate

Contains sugar: Sucrose 2250,00 mg, Liquid sorbitol (70 %) 500,00 mg

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ASTHAVENT SYURP with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What ASTHAVENT SYRUP is and what it is used for
2. What you need to know before you take ASTHAVENT SYRUP
3. How to take ASTHAVENT SYRUP
4. Possible side effects
5. How to store ASTHAVENT SYRUP

6. Contents of the pack and other information.

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

ASTHAVENT SYRUP (salbutamol) belongs to a class of medicine known as selective beta-2-adrenergic agonists, which can be used to relax the muscles of the airways.

ASTHAVENT SYRUP is indicated for the treatment of:

- Bronchial asthma
- Emphysema
- Chronic obstructive bronchitis

2. What you need to know before you take ASTHAVENT SYRUP

Do not take ASTHAVENT SYRUP if you:

- are hypersensitive (allergic) to salbutamol or any of the other ingredients of ASTHAVENT SYRUP (listed in **Section 6**).
- If you are taking a medicine called a beta-blocker (used to the treatment of high blood pressure or heart disorders).
- If you have an overactive thyroid gland.
- If you have a heart disorder.
- If you are taking a medicine called a monoamine oxidase inhibitor (used in the treatment of mood disorders such as depression), or if you have stopped it within the last 14 days.
- Threatened abortion (potential miscarriage) during the first 6 months of pregnancy.

ASTHAVENT SYRUP should not be used to prevent premature labour during the first or second trimesters of pregnancy.

Warnings and Precautions

Take special care with ASTHAVENT SYRUP:

- Your body may develop a tolerance (get used to) to ASTHAVENT SYRUP after continued use. If your asthma gets worse, consult your doctor for additional or other treatment.
- If you are about to undergo an operation where you will be put to sleep during the operation.
- If you have an aneurysm (abnormal widening or ballooning of a portion of an artery due to weakness in the wall of the blood vessel).
- If you have diabetes (high blood sugar).
- If you have an eye disorder called glaucoma.
- If you participate in certain sports where the use of ASTHAVENT SYRUP may be prohibited.
- If you feel that the relief from taking ASTHAVENT SYRUP becomes less, this may indicate that your asthma is not under control. Please consult your doctor for additional or other treatment.

Children

There is no experience with ASTHAVENT SYRUP in children younger than 2 years.

Other medicines and ASTHAVENT SYRUP

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

Tell your doctor if you are taking any of the following:

- Beta-blockers (medicines used to treat high blood pressure or heart disorders).
- Corticosteroids (used to treat conditions with pain, swelling and inflammation).
- Diuretics (water tablets).
- Other medicines used to treat asthma (such as aminophylline or theophylline).
- Certain medicines used to treat heart disorders (such as digoxin or quinidine).
- Monoamine oxidase inhibitors or tricyclic antidepressants (used to treat mood disorders such as depression) (see DO NOT TAKE ASTHAVENT SYRUP).
- High blood pressure medicines (such as reserpine and methyldopa).
- Anti-diabetic medicines.

ASTHAVENT SYRUP with food, drink and alcohol

ASTHAVENT SYRUP may be taken with or without food.

Pregnancy, breastfeeding and fertility

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 SYRUP.

Driving and using machinery

It is not always possible to predict to what extent ASTHAVENT SYRUP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ASTHAVENT SYRUP affects them.

ASTHAVENT SYRUP contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ASTHAVENT SYRUP.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Contains 2,25 g of sucrose per dose. This should be taken into account in patients with diabetes mellitus.

May be harmful to the teeth.

ASTHAVENT SYRUP contains sorbitol

ASTHAVENT SYRYP contains 500,00 mg liquid sorbitol (70 %) in each 5 mL which is equivalent to 350 mg/5 mL

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

3. How to take ASTHAVENT SYRUP

Do not share medicines prescribed for you with any other person.

Always take ASTHAVENT SYRUP 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.

The usual dose is:

Children:

2 to 6 years: 2,5 to 5 mL ($\frac{1}{2}$ to 1 measureful) three to four times daily.

Over 6 years: 5 mL (1 measureful) three to four times daily.

Adults:

5 to 10 mL (1 to 2 measuresful) three to four times daily.

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

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

If you take more ASTHAVENT SYRUP than you should

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

If you forget to take ASTHAVENT SYRUP

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take ASTHAVENT SYRUP at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

4. Possible Side Effects

ASTHAVENT SYRUP can have side effects

Not all side effects reported for ASTHAVENT SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ASTHAVENT SYRUP, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ASTHAVENT SYRUP. 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:

- Low blood pressure (light-headedness, dizziness, and fainting),
- anxiety, restlessness, trouble sleeping, confusion, irritability, nervousness,
- changes in your mental state,
- irregular or higher than normal heartbeat,
- difficulty breathing,
- tremors (shaking), particularly in the hands.

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:

- Headache

Less frequent side effects:

- Hives,
- decreased appetite,
- nausea (feeling sick), vomiting (being sick),

- increased saliva in mouth, increase sweating,
- muscle cramps,
- difficulty in urination, urinary retention,
- weakness.

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 “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of ASTHAVENT SYRUP.

5. How to store ASTHAVENT SYRUP

- Store at or below 25 °C.
- Protect from light.
- Store all medicines out of reach of children.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not use after the expiry stated on the label/carton/bottle.

6. Contents of the pack and other information

What ASTHAVENT SYRUP contains

The active substance is 2 mg salbutamol as salbutamol sulphate per 5 mL.

The other ingredients are citric acid monohydrate, colour carmoisine supra, liquid sorbitol 70 %, methyl hydroxybenzoate (methyl parahydroxybenzoate), orange four flavour, propyl hydroxybenzoate (propyl parahydroxybenzoate), purified water, sodium citrate dihydrate, sodium chloride and sucrose.

What ASTHAVENT SYRUP looks like and contents of the pack

ASTHAVENT SYRUP: A pink coloured clear solution with a characteristic fruity flavour.

ASTHAVENT SYRUP is presented a carton containing a 100 mL amber PET bottle.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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