

Asthalin HFA Inhaler[®]

Salbutamol Pressurised Inhalation, Suspension BP (100 micrograms / dose)

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What ASTHALIN INHALER is used for

Asthalin inhaler is used for the relief and prevention of asthma symptoms. It should be used to relieve symptoms when they occur, and to prevent them in those circumstances recognised by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure).

How ASTHALIN INHALER works

Asthalin inhaler contains a medicine called salbutamol. This belongs to a group of medicines called bronchodilators. Bronchodilators relax the muscles in the walls of the small airway passages in the lungs.

Asthalin

- Helps to open up the airways in your lungs, making it easier for you to breath.
- Helps to relieve chest tightness, wheezing and cough associated with asthma.

Asthalin inhaler contains a propellant called HFA 134a. This is less harmful to the environment than older inhalers.

Before you use ASTHALIN INHALER

- When you must not use it

Do not use Asthalin inhaler:

- If you are allergic (hypersensitive) to salbutamol sulphate or any of the other ingredients of this medicinal product.

If you think any of these apply to you, do not use Asthalin until you have checked with your doctor.

Pregnancy and breastfeeding

Asthalin inhaler is not usually recommended for use during pregnancy. If you are pregnant, or think you could be, or if you are planning to become pregnant, do not take Asthalin inhaler without checking with your doctor. Your doctor will consider the benefit to you and the risk to your baby of taking Asthalin inhaler while you are pregnant.

It is not known whether the ingredients of Asthalin inhaler can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take Asthalin inhaler.

- Before you start to use it

Before you use Asthalin, your doctor needs to know if you:

- have an overactive thyroid gland

Check with your doctor if you think any of these may apply to you.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go to hospital.

Some medicines may affect how Asthalin works or make it more likely that you will have side effects. These include:

- Beta-blockers (such as propranolol) used to treat high blood pressure or a heart condition.

- xanthine derivatives (such as theophylline) or Steroid medicines to treat asthma.
- Water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.

Your doctor will monitor your potassium levels if you are taking any of the medicines listed here.

Your doctor or pharmacist will decide if you should take Asthalin inhaler with these medicines.

How to use ASTHALIN INHALER

-How much to use

Adults

- to relieve asthma - The usual starting dose is one or two puffs (100-200 micrograms once a day)
- to prevent asthma - The usual starting dose is two puffs (200 micrograms) before exercise or exposure to a "trigger".
- for long term treatment - The usual starting dose is two puffs (200 micrograms) up to four times a day.

Children

- to relieve asthma - The usual starting dose is one puff (100 micrograms) once a day. The dose may be increased to two puffs (200 micrograms) if required.
- to prevent asthma - The usual starting dose is one puff (100 micrograms) before exercise or exposure to a "trigger". The dose may be increased to two puffs (200 micrograms) if required.
- for long term treatment - The usual starting dose is two puffs (200 micrograms) up to four times a day.

The maximum dose is 8 puffs (800 micrograms) in a 24 hour period. Do not inhale more puffs or use your inhaler more often. Tell your doctor if your medicine does not seem to be working as well as usual as your

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asthma may be getting worse and you may need a different medicine.

Some people find it difficult to release a puff of medicine just after they start to breathe in. A spacer device (a specially designed plastic or metal tube that is fitted to an inhaler on one end, while the patient breathes normally on the other end) may help to overcome this problem. Your doctor, nurse or pharmacist will be able to advise you about this.

Instructions for Use:

Please refer section below for Instructions for Use of:

- 1) Asthalin HFA Inhaler without dose indicator
- 2) Asthalin HFA Inhaler with dose indicator

-When to use it

Always use your Asthalin inhaler exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

-How long to use it

Take Asthalin inhaler for as long as your doctor recommends. Do not stop unless your doctor advises you to.

-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

If you use too much Asthalin inhaler, contact your doctor or pharmacist for advice. If possible, show them the Asthalin inhaler pack.

The symptoms of overdose include:

- Low blood potassium level
- Lactic acidosis (buildup of lactic acid in the body)

While you are using ASTHALIN INHALER

- Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

If your medicine does not seem to be working as well as usual, talk to your doctor as soon as possible. Your chest problem may be getting worse and you may need a different medicine. Do not take extra doses of Asthalin inhaler unless your doctor tells you to.

Side effects

Like all medicines, Asthalin inhaler can cause side effects, although not everybody gets them.

Allergic Reactions

These are very rare in people taking salbutamol. Signs include:

- skin rash, (hives) or redness
- swelling, sometimes of the face or mouth (angioedema)
- becoming very wheezy, coughing or having difficulty in breathing,
- suddenly feeling weak or light headed (may lead to collapse or loss of consciousness)

Contact a doctor immediately if you get any of these symptoms. Stop taking Asthalin inhaler.

Common side effects

- feeling shaky
- headache
- heart beating faster

Uncommon side effects

- irregular heart beat (palpitations)

- mouth and throat irritation
- muscle cramps

Rare side effects

- a low level of potassium in your blood
- increased blood flow to your extremities (widening of the blood vessels)

Very rare side effects

- cardiac arrhythmias (irregular heartbeat)
- allergic reactions
- feeling unusually active, such as restlessness and excitability

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for adverse Drug Reaction monitoring by visiting the web site: npra.gov.my [Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ASTHALIN INHALER

-Storage

- Keep out of the reach and sight of children.
- Do not use Asthalin after the expiry date shown on the pack.
- Store below 30°C. Protect from direct sunlight. Do not freeze.
- Replace the mouthpiece cover firmly and snap it into position.
- If the inhaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few minutes before use. Never use anything else to warm it up.
- The container contains a pressurized liquid. Do not expose to temperature higher than 50°C. Do not puncture, break or burn the inhaler even when it is empty.

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-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

NPRA Serial Number

NPRA (R2/2)231023/1163

Product description

- What it looks like

Asthalin HFA inhaler is a milky white homogenous suspension filled in a aluminium containers in a CFC free propellant gas. The aluminium container is fitted with a metering valve and a plastic oral actuator.

For Asthalin HFA inhaler with dose indicator, the plastic actuator will have a dose indicator.

- Ingredients

Salbutamol Sulphate (equivalent to Salbutamol 100 mcg)

-Inactive ingredients:

Tetrafluoroethane (Propellant 134a)

-MAL Number

MAL20041029AC

Manufacturer

Cipla Ltd.

At Medispray laboratories Pvt Ltd,
344/345 Kundaim industrial estate,
Kundaim , Goa-403115, India

Product Registration Holder

CIPLA MALAYSIA SDN BHD
Suite 1101, Amcorp Tower,
Amcorp Trade Centre,
18 Persiaran Barat,
46 050 Petaling Jaya,
Selangor, Malaysia.

Date of Revision

15/03/2024

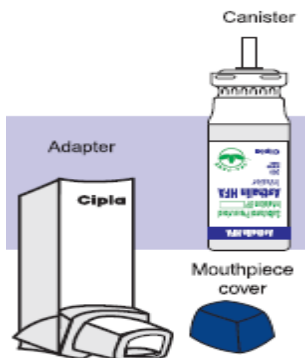
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(1) ASTHALIN HFA INHALER WITHOUT DOSE INDICATOR

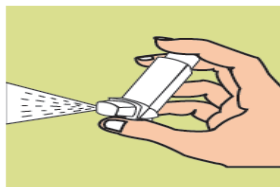
Instruction for Use

Parts of the Inhaler:



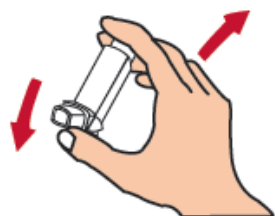
Testing your inhaler

Before using your Inhaler for the first time, or if it has not been used for a week or more, shake it well and then "test fire" it i.e., release one puff into the air.



Using your Inhaler

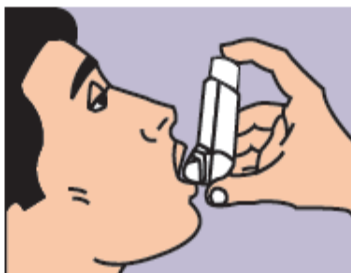
1. Remove the mouthpiece cover, and check that the mouthpiece is clean. Shake the inhaler well before each use.



2. Hold the inhaler as shown, between index finger and thumb. Breathe out gently, through your mouth and immediately place the mouthpiece in your mouth between your teeth and close your lips around it (Do not bite it).



3. Tilt your head slightly backwards. Start breathing in slowly through your mouth. As you breathe in, press down the canister to release one dose while continuing to breathe in steadily and deeply.



4. Remove the Inhaler from your mouth and hold your breath for 10

seconds, or for as long 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 steps 2 and 3. It is important to breathe in as slowly through your mouth just before pressing the canister. Practise in front of the mirror for the first few times.



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If you see 'mist' coming from the top of the inhaler or the sides of your mouth, start again from step 1. This escaping mist indicates incorrect technique.

Parents must assist those children who need help in using the inhaler correctly.



Cleansing

Clean your inhaler at least once a week as follows:

1. Gently pull the metal canister out of the adapter of the inhaler. Remove the mouthpiece cover.
2. Rinse the adapter and mouthpiece cover in warm water. Do not put the metal canister into water.
3. Shake well to remove excess water.
4. Leave to dry in warm place. Avoid excess heat.
5. Replace the canister and the mouthpiece cover correctly.



Warning

Use only as directed by your doctor. If the recommended dose does not provide the relief of symptoms or symptoms become worse, consult your doctor.

The metal canister is pressurized. Do not puncture, break or burn it even when empty.

Keep away from eyes.

Keep away from children.

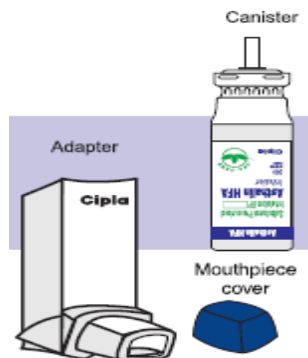
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(2) ASTHALIN HFA INHALER WITH DOSE INDICATOR

Instruction for Use

Parts of the Inhaler:

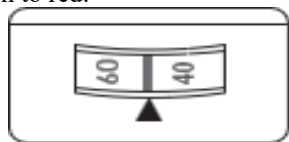


Your ASTHALIN HFA inhaler now comes with a dose indicator. It shows the number of puffs in the inhaler. As you use the inhaler, the dose indicator will countdown and indicate the number of puffs remaining.

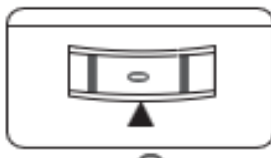
Remember, the dose indicator counts every dose but shows the number at intervals of 20. Thus, as the inhaler is used, the dose indicator will count down and show the numbers 200, 180, 160, 140, 120, 100, 80, 60, 40, 20 and 0.

HOW TO KNOW THAT YOUR ASTHALIN HFA INHALER IS GETTING OVER

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



This indicates that fewer doses are remaining in the inhaler. You should now consider getting a new inhaler or ask your doctor if you need another one. When the dose indicator displays '0', this means that there is no more medicine left in the inhaler and you need to discard the inhaler. Your inhaler may not feel empty and it may continue to operate, but you will not get the right amount of medicine, if you keep using it beyond '0'.



Testing your inhaler

A. Remove the cap from the mouthpiece and make sure that the mouthpiece is clean.

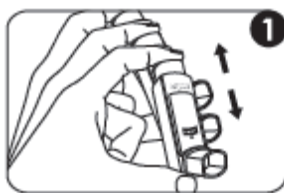
B. Hold the inhaler away from your face. Shake it well and release two puffs into the air.



C. Your ASTHALIN HFA inhaler is now ready for use. If you have not used your inhaler for a week or more, shake well and release one puff into the air.

Using your Inhaler

1. Sit or stand upright. Remove the mouthpiece cap & shake the inhaler 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 inhaler in your mouth between your teeth & close your lips around it (do not bite it). Start

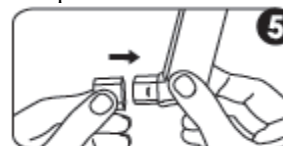
breathing in slowly through your mouth. Press down the canister firmly & fully to release one spray while continuing to breathe in slowly & deeply.



4. Remove the Inhaler from your mouth & hold your breath for 10 seconds, or for as long as is comfortable. Breathe out normally.



If another puff is required, wait for at least 1 minute. Shake inhaler well & repeat steps 2 to 4. After use, replace the mouthpiece cap firmly & snap it into position.



IMPORTANT:

Do not rush steps 2, 3 & 4. It is important you start to breathe in slowly before releasing a puff. To ensure correct use of the inhaler, use it in front of a mirror for the first few times.

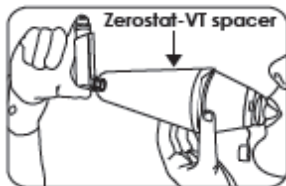


If you see "mist" coming from the top of the inhaler or the sides of your mouth, start again from step 1. This escaping mist indicates incorrect technique.

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In case of difficulty in using the inhaler correctly, you may use it along with a Zerostat-VT spacer.



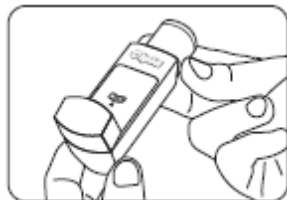
For children: Parents must assist those children who need help in using the Asthalin HFA inhaler correctly with/without a spacer.



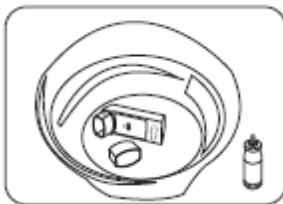
Cleaning your Asthalin HFA inhaler

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.



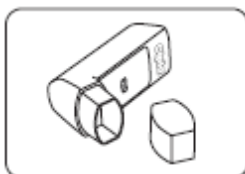
2. Immerse the actuator and the mouthpiece cap in warm water. Do not put the metal canister in water.



3. Next, rinse the actuator and the mouthpiece cap thoroughly under running tap water.



4. Shake well to remove excess water.
5. Leave it to air-dry. Avoid excess heat.



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