

# APO-Salbutamol

## *Inhalation Ampoules*

*Contains the active ingredient salbutamol sulfate*

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### Consumer Medicine Information

**For a copy of a large print leaflet, Ph: 1800 195 055**

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## What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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## What is this medicine used for

Salbutamol is inhaled into your lungs to relieve the symptoms of asthma and other breathing problems.

It may also be used before exercise or at other times to keep your air passages open if you start to wheeze or have difficulty breathing each time you exert yourself.

Asthma is a disease where the lining of the lungs becomes inflamed (red and swollen), making it difficult to breathe. This may be due to an allergy to house dust mites, smoke,

air-borne pollution and other irritants.

Salbutamol belongs to a family of medicines called bronchodilators (beta-2-agonists). These work rapidly to open up the air passages in the lungs of people suffering from asthma, bronchitis, emphysema and other breathing problems.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive

**This medication is delivered directly to your lungs through a device called a nebuliser.**

APO-Salbutamol Inhalation Ampoules may be used in children aged between 4 and 12 years of age.

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## Before you use this medicine

### ***When you must not use it***

**Do not use this medicine if you have an allergy to:**

- any medicine containing salbutamol
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not use this medicine to stop a miscarriage or premature labour.**

**Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start using this medicine, talk to your doctor.**

### ***Before you start to use it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- thyroid problems
- heart problems
- liver problems
- kidney problems
- high blood pressure
- diabetes
- glaucoma

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before you start using this medicine.**

***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines may interact with salbutamol. These include:

- corticosteroids
- other medicines used to help breathing problems, e.g. xanthine derivatives (theophylline, aminophylline) and inhaled anticholinergics such as ipratropium
- diuretics (also known as fluid or water tablets), used to lower blood pressure
- medicines for heart problems such as digoxin
- imipramine, used for treating depression
- chlordiazepoxide, used for treating anxiety
- chlorpromazine, used for treating mood disorders
- other beta-agonists or medicines called sympathomimetic amines which may be found in medicines for hay fever, coughs and colds (e.g. ephedrine) and medicines for weight reduction (e.g. phentermine)
- medicines used to treat high blood pressure and heart problems, such as beta blockers
- medicines, including eye drops, used for treating glaucoma

These medicines may be affected by salbutamol or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

**Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.**

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**How to use this medicine**

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**Follow all directions given to you by your doctor carefully.**

Their instructions may be different to the information in this leaflet.

***How much to use***

**Use salbutamol only as directed by your doctor.**

If you do not follow your doctor's instructions correctly, your breathing problems may not be controlled.

Your doctor has carefully chosen your dose of salbutamol according to your medical condition, your age, your body weight, any other medical conditions that you may have, and whether you are using or taking other medicines at the same time.

The usual dose is 5 mg for an adult and 2.5 mg for a child (4 - 12 years), given via nebuliser every four to six hours.

Elderly people may start with a lower dose and build up gradually.

**Do not stop using your medicine, or change the dosage, without checking with your doctor.**

***How to use it***

**Do not swallow or inject the liquid in the salbutamol inhalation ampoule.**

The contents of the salbutamol inhalation ampoule are inhaled through a nebuliser according to the manufacturer's instructions. The nebuliser changes the solution into a fine mist and delivers the medicine to your lungs when you inhale the mist through the mask.

**Caution: Make sure that the mist does not get into your eyes.**

**STEP 1:**

Remove the strip of ampoules from the carton and tear one ampoule from the strip. Open only one foil pack at a time, and use all 5 ampoules before opening the next foil pack.



**STEP 2:**

Never use an ampoule that has previously been opened. The ampoule may be opened by carefully holding the ampoule upright and twisting the top off.



**STEP 3:**

The contents of the ampoule should be squeezed out into the nebuliser bowl.



The nebuliser should be assembled and used as directed by your doctor. After using the nebuliser, discard any solution remaining in the nebuliser bowl. Follow the manufacturer's instructions on how to clean your nebuliser.

## **IMPORTANT:**

A fresh ampoule of salbutamol must be used for each dose.

After the full dose has been given, any solution remaining in the nebuliser must be thrown away. Nebulisers must be cleaned after use according to manufacturer's instructions.

**If you do not understand the instructions, ask your doctor or pharmacist for help.**

### ***How long to use it for***

**Continue taking your medicine for as long as your doctor tells you.**

Salbutamol helps control your condition but does not cure it. Therefore, you will need to use the medicine for as long as your doctor tells you.

### ***If you forget a dose***

If you have been told to use salbutamol regularly and forget a dose, do not worry. Just use the next dose at the normal time or earlier if you become wheezy or feel tight in the chest.

**Do not use a double dose to make up for missed doses.**

This may increase the chance of you experiencing side effects.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to use your medicine, ask your pharmacist for some hints to help you remember.**

### ***If you use too much (overdose)***

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning.**

**You may need urgent medical attention.**

If you use too much salbutamol, you may, have a fast or irregular heartbeat, feel shaky or start to tremble. Trembling may affect the whole body, especially the fingers.

These symptoms may be normal side effects of using salbutamol.

However, if they are severe or do not go away, it may be that you have used too much.

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## **While you are using this medicine**

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### ***Things you must do***

**If this medicine does not help your breathing as much as usual, tell your doctor as soon as possible.**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using this medicine.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant or start to breastfeed while using this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are using this medicine.**

It may interfere with the results of some tests.

**Keep all your doctor's appointments so that your progress can be checked.**

Go to your doctor regularly for a check-up. This is important to ensure your breathing problem is controlled properly.

Your doctor may also do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**Tell your doctor if, for any reason, you have not used your medicine exactly as directed.**

Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

### ***Things you must not do***

**Do not use this medicine to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop using your medicine or lower the dosage without checking with your doctor.**

**Do not take any other medicines for your breathing problems without checking with your doctor.**

**Do not mix any other medicines in the nebuliser solution.**

**Do not allow salbutamol, or any other nebuliser solution or the nebulised mist, to come into contact with your eyes.**

**Do not swallow or inject the nebuliser solution.**

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using this medicine.**

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

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

If available, try a different fast-acting asthma medicine as soon as possible.

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- a feeling of warmth or flushing
- sore mouth or throat
- headache
- nausea
- muscle cramps
- feeling restless or tense, or unusually active with excitability
- hyperactivity in children
- feeling shaky or trembling – trembling may affect the whole body, especially the fingers

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

**Tell your doctor as soon as possible if you notice any of the following:**

- faster than normal heartbeat
- ketoacidosis resulting from high blood sugar (e.g. sweet-smelling breath, sweating, light-headedness, dizziness, headache or lack of concentration, irritability, tearfulness, weakness, trembling or shaking, hunger, and/ or numbness around the lips and tongue), which has been seen in diabetic patients.

These may be serious side effects and you may need medical attention.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- your breathing problem is not relieved by your medicine, or is getting worse
- fast, pounding or irregular heartbeat
- feeling weak, confused and/or depressed
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## Storage and disposal

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**Keep your medicine in their original foil packs until it is time to use them.**

If you take the ampoules out of the foil pack, they may not keep as well.

Once you have opened each foil pack, you need to note down the date of opening the foil lid.

**This medicine should be used within 3 months of opening the foil lid.**

Do not use any ampoules left in the tray after this date.

**Keep your medicine in a cool dry place, where the temperature will stay below 25°C. Protect it from light.**

**Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## Disposal

**If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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The solution in these ampoules is sterile and does not contain preservatives.

### *What it looks like*

**APO-Salbutamol Inhalation Ampoules equivalent to salbutamol 2.5 mg/2.5 mL**

Plastic unit dose ampoules containing salbutamol in a clear colourless to pale yellow, sterile, isotonic solution for inhalation. AUST R 142566.

**APO-Salbutamol Inhalation Ampoules equivalent to salbutamol 5 mg/2.5 mL**

Plastic unit dose ampoules containing salbutamol in a clear colourless to pale yellow, sterile, isotonic solution for inhalation. AUST R 142567.

Available in packs of 30 (5 ampoules per foil pouch).

### *Ingredients*

APO-Salbutamol Inhalation Ampoules contain salbutamol (as salbutamol sulfate) 2.5 mg or 5 mg per 2.5 mL as the active ingredient.

It also contains the following inactive ingredients:

- water for injection
- sodium chloride
- sulfuric acid (used to adjust pH)

### *Sponsor*

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