

APO-Salbutamol

Inhalation Ampoules

Contains the active ingredient salbutamol (sal-bew-tam-ol) sulphate

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before you start to use this medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

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.

It is delivered directly to your lungs through a device called a nebuliser.

How it works

Salbutamol belongs to a family of medicines called bronchodilators (beta-2-agonists). These work rapidly to open up the air passages in your lungs.

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 opens up the air passages in people suffering from asthma, bronchitis, emphysema and other breathing problems.

This medicine may be used for the management of other conditions that are not mentioned above. Your doctor will be able to tell you about

the specific condition for which you have been prescribed salbutamol.

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

There is no known evidence to show that this medicine is addictive

Use in children

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

Things to consider before you use this medicine

When you must not use it

Do not use this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, salbutamol or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: 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; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor

immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to use it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - thyroid problems
 - heart problems
 - liver problems
 - kidney problems
 - high blood pressure
 - diabetes
 - glaucoma
3. You are currently pregnant or you plan to become pregnant. Do not use this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breast-feed. Do not use this medicine whilst breastfeeding.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available 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 (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 taking this medicine.

Other interactions not listed above may also occur.

How to use this medicine

Follow all directions given to you by your doctor carefully.

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

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

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 take the next dose at the normal time or earlier if you become wheezy or feel tight in the chest.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to the Accident and Emergency Department at your nearest hospital if you think you or anyone else may have used too much salbutamol.

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.

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

This is important to ensure your breathing problem is controlled properly.

Tell your doctor if, for any reason, you have not taken 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:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.

- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.
- Take any other medicines for your breathing problems without checking with your doctor.
- Mix any other medicines in the nebuliser solution.
- Allow salbutamol, or any other nebuliser solution or the nebulised mist, to come into contact with your eyes.
- Swallow or inject the nebuliser solution.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are using salbutamol or if you have any questions or concerns. Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- a feeling of warmth
- sore mouth or throat
- headache
- nausea
- muscle cramps
- feeling restless or tense
- hyperactivity in children
- feeling shaky or trembling.
Trembling may affect the whole body, especially the fingers

The above list includes side effects which are usually mild.

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.

You may need medical attention.

If any of the following happen, do not use any more of your medicine and either 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

These side effects are usually rare but may be serious and require urgent medical attention.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to salbutamol, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Keep APO-Salbutamol Inhalation Ampoules 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. APO-Salbutamol Inhalation Ampoules 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 APO-Salbutamol, or the ampoules have passed their expiry date, ask your pharmacist what to do with any ampoules left over.

Product description

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 solution for inhalation.

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 solution for inhalation.

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

Ingredients

APO-Salbutamol Inhalation Ampoules contain salbutamol (as salbutamol sulphate) 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).

Australian Registration Numbers

APO-Salbutamol Inhalation Ampoules equivalent to salbutamol 2.5 mg/2.5 mL: AUST R 142566.

APO-Salbutamol Inhalation Ampoules equivalent to salbutamol 5 mg/2.5 mL: AUST R 142567.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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