

Apo-Ipratropium

contains the active ingredient, ipratropium bromide

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

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about ipratropium.

It does not contain all the available information.

It does not take the place of talking to your doctor and pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on the medicine may be available. Speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

All medicines have benefits and risks. Your doctor has weighed the risks of you using this medicine against the benefits this medicine is expected to have for you.

Keep this leaflet with the medicine.

You may want to read it again.

What ipratropium is used for

The name of your medicine is Apo-Ipratropium. It contains the active ingredient, Ipratropium (as ipratropium bromide).

How it works

Ipratropium can be used to prevent or to treat the narrowing of the airways associated with asthma.

Ipratropium can also be used to relieve any reversible airways blockage associated with problems such as repeated infections affecting the airways.

Ipratropium works by opening up the narrowed airways to assist breathing.

Your doctor may have prescribed this medicine for another reason.

There is no evidence that ipratropium is addictive.

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

This medicine is not expected to affect your ability to drive a car or operate machinery, but make sure you know how it affects you before driving.

Before you take ipratropium

When you must not use it

Do not use this medicine if you have had an allergic reaction to it or other medicines containing ipratropium or any of the ingredients listed at the end of this leaflet.

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, muscle pain tenderness or joint pain or rash, itching or hives on the skin.

Do not take this medicine if:

the packaging is torn or shows signs of tampering

- **the expiry date (EXP) on the pack has passed.**
- If you use this medicine after the expiry date has passed, it may not work as well or it may make you feel sick.

If you are not sure whether you should start using ipratropium, talk to your doctor.

Before you start to use it

You must tell your doctor:

- 1. if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**
- 2. if you have or have ever had any other health problems/medical conditions, including:**
 - glaucoma, high pressure in the eye
 - difficulty in passing urine
 - constipation, inability to open bowels
 - cystic fibrosis.
- 3. if you are pregnant or intend to become pregnant.**

Your doctor will discuss the risks and benefits of using ipratropium during pregnancy.

- 4. if you are breast-feeding or plan to breast-feed.**

Your doctor will discuss the risks and benefits of using ipratropium when breast-feeding.

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

Taking other medicines

Tell your doctor if you are taking/using any other medicines, including medicines that you buy without a

prescription from your pharmacy, supermarket or health food shop.

How to use this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to use

Ipratropium is to be used under the direction of a doctor. Your doctor will recommend a suitable dose for you.

How to use it

Ipratropium is to be delivered from an efficient device, called a nebuliser, which produces a fine mist to breathe in.

Opening instructions for the single dose units:

1. Twist a single unit downwards to remove from the strip.
2. Flick the single dose unit so that the solution flows to the bottom.
3. Hold the base of the single dose unit and break the seal with a quick twisting action.
4. Snap off the top.

5. Squeeze the contents of the single dose unit into the nebuliser bowl.

Ipratropium solution must not enter the eyes, be injected or swallowed.

Unless directed otherwise by your doctor or pharmacist dilute the contents of the single dose unit to 2-3mL with normal saline and nebulise until the entire volume of solution is inhaled.

How long to use it

Your doctor will decide how long you will need to use ipratropium.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have used too much or swallowed any of the ipratropium single dose units.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers of these places/services handy.

If you use too much ipratropium you may have:

- dry mouth

- fast heart rate
- difficulty in passing urine
- constipation, inability to open bowels
- eyesight difficulty
- red, painful eyes with brow-ache or headache and possibly followed by nausea or vomiting.

While you are using this medicine

Things you must do

If the symptoms of your asthma do not improve within a few days, or if they become worse, tell your doctor.

If you become pregnant while you are using this medicine tell your doctor.

If you are about to start taking/using any new medicine, tell your doctor and pharmacist that you are using ipratropium.

Tell all the doctors, dentists and pharmacists who are treating you that you are using ipratropium.

Things you must not do

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

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

Things to be careful of

Be careful driving or operating machinery until you know how ipratropium affects you.

Ipratropium generally does not cause any problems with your ability to drive a car or operate machinery.

Side effects

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

Like other medicines, ipratropium can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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

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

- mouth / throat irritation
- cough
- headache
- nausea

- indigestion
- constipation
- dizziness.

These are all mild side effects of ipratropium.

Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

- difficulty in passing urine
- red, painful eyes with brow-ache or headache and possibly followed by nausea or vomiting
- eye pain
- dilated pupils of the eyes
- shortness of breath or difficulty breathing
- swelling with fluid in the tissues
- skin rash, may be itchy
- changes in the way your heart beats e.g. if you notice it beating faster or the beats are irregular.

These are all serious side effects of ipratropium. You may need urgent medical attention.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using this medicine

Storage

Keep your ipratropium single-dose units in their original packs until it is time to use them.

If you take ipratropium single-dose units out of the pack, it may not keep well.

Keep it in a cool dry place, where the temperature stays below 25 degrees C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

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.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or

pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What Apo-Ipratropium looks like

Apo-Ipratropium is a clear, aqueous isotonic, preservative-free nebuliser solution, in single-use ampoules. They are available in packs of 30's.

Ingredients

Active Ingredient:

Apo-Ipratropium solution contains the active ingredient, ipratropium (as ipratropium bromide).

Inactive Ingredients:

Apo-Ipratropium also contains the following inactive ingredients:

- sodium chloride
- hydrochloric acid
- water for injection.

Australian Registration Numbers

Apo-Ipratropium 250mcg/1mL solution: AUST R 151089.

Apo-Ipratropium 500mcg/1mL solution: AUST R 151090.

Sponsor

Sigma Pharmaceuticals

(Australia) Pty Ltd

A.C.N. 004 118 594

96 Merrindale Dve

Croydon Victoria 3136

Distributor

Apotex Pty Ltd

ABN 52 096 916 418

66 Waterloo Road

North Ryde NSW 2113

Australia

Apotex Pty Ltd is the licensee of the registered trade marks AX logo, APO and APOTEX from the registered proprietor, Apotex Inc.

This leaflet was prepared in:

April 2008 and updated in May 2009.