

APO-Ipratropium

Contains the active ingredient ipratropium bromide

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

This leaflet answers some common questions about APO-Ipratropium. It does not contain all the available information. It does not take the place of talking to your doctor and pharmacist.

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

Keep this leaflet with the medicine.

You may want to read it again.

What APO-Ipratropium is used for

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

It is used to prevent or to treat the narrowing of the airways associated with asthma.

It 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.

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.

There is no evidence that ipratropium is addictive.

Before you use it

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 atropine 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 use it 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.

Talk to your doctor if you are not sure whether you should start using APO-Ipratropium.

Before you start to use it

Tell your doctor if you:

- 1. have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**
- 2. 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. are pregnant or intend to become pregnant.

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

4. are breast-feeding or plan to breast-feed.

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

5. are planning to have surgery or an anaesthetic.

6. are receiving or are planning to receive dental treatment.

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 it

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

How much to use

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

How to use it

APO-Ipratropium is a solution which is used in 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.

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

Diluted solutions should be freshly prepared before use and any solution remaining in the nebuliser on completion of inhalation should be discarded.

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

How long to use it

Your doctor will decide how long you will need to use this medicine.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too much or swallowed any of the APO-Ipratropium single dose units.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose include:

- dry mouth
- fast heart rate
- eyesight difficulty
- red, painful eyes with brow-ache or headache and possibly followed by nausea or vomiting.

While you are using it

Things you must do

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are going to have surgery or an anaesthetic or are going into hospital.

Tell any other doctors, dentists and pharmacists who are treating you that you are using APO-Ipratropium.

Things you must not do

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

Do not use it to treat any other conditions unless your doctor tells you to.

Things to be careful of

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

Be careful driving or operating machinery until you know how APO-Ipratropium affects you.

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

Possible Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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:

- dryness of the mouth or throat irritation
- cough
- headache
- nausea
- indigestion
- constipation
- dizziness.

These are all common, usually mild side effects of this medicine.

Tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital if you notice any of the following symptoms:

- 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 APO-Ipratropium. You may need urgent medical attention.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

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

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

You may not experience any of them.

After using it

Storage

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

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

Keep this medicine in a cool dry place, where the temperature stays below 25°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.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What it looks like

APO-Ipratropium is available in two strengths; 250 mcg/1 mL or 500 mcg/1 mL.

They are a clear, aqueous isotonic, preservative-free nebuliser solution in single-use plastic ampoules.

Available in packs of 30.

Ingredients

Active ingredient:

Each ampoule contains ipratropium bromide [equivalent to either 250 mcg/mL or 500 mcg/mL] as the active ingredient.

Inactive ingredients:

- sodium chloride
- hydrochloric acid
- water for injections.

APO-Ipratropium does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

Sponsor

Aspen Pharma Pty Ltd

34-36 Chandos Street

St Leonards NSW 2065

Australia

Distributor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Australian Registration Numbers

- 250 mcg/1 mL: AUST R 151089
- 500 mcg/1 mL: AUST R 151090.

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