

Ipratrin® uni-dose

Ipratrin® Adult uni-dose

contains the active ingredient ipratropium bromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ipratrin uni-dose and Ipratrin Adult uni-dose.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about using this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Ipratrin is used for

Ipratrin is used to treat:

- asthma
- chronic obstructive bronchitis
- people who have difficulty breathing during or after surgery using assisted ventilation

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 or other irritants.

Chronic obstructive bronchitis is a lung condition that can cause difficulty in breathing, wheeziness and constant coughing.

Ipratrin contains the active ingredient ipratropium bromide. It belongs to a group of medicines called anticholinergic bronchodilators.

Ipratrin opens up the air passages in people suffering from asthma, chronic bronchitis and difficulty breathing during or after surgery.

It begins to act quickly after use but may take up to 2 hours to give maximum benefit.

Ask your doctor if you have any questions about why Ipratrin has been prescribed for you.

Your doctor may have prescribed it for another reason.

Ipratrin is available only with a doctor's prescription.

There is no evidence that Ipratrin is addictive.

Before you use Ipratrin

When you must not use it

Do not use Ipratrin if you have an allergy to:

- ipratropium bromide or any other medicines used to treat breathing problems
- similar medicines which contain atropine or medicines like atropine
- any of the ingredients listed at the end of this leaflet.
- any other anticholinergic medicines.

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 Ipratrin after the expiry date printed on the ampoule or pack, or if the packaging is torn or shows signs of tampering.

If you take this medicine after the expiry date has passed, it may not work as well.

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, contact your doctor or pharmacist.

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 are pregnant or intend to become pregnant.

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

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

Your doctor or pharmacist will discuss the possible risks and benefits of using Ipratrin during breastfeeding.

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

- glaucoma (high pressure in the eye)

- difficulty or pain when passing urine
- constipation
- cystic fibrosis
- hyperreactive airway.

If you have not told your doctor about any of the above, tell him/her before you start using Ipratrin.

Taking other medicines

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

Some medicines and Ipratrin may interfere with each other. These include:

- medicines used to treat heart problems such as adrenaline
- medicines used to treat asthma or a lung condition called chronic obstructive pulmonary disease (COPD) such as theophylline and salbutamol or tiotropium
- other nebuliser solutions such as disodium cromoglycate that contain the preservative benzalkonium chloride.

This is because some nebuliser solutions may not mix well with Ipratrin and may need to be nebulised separately.

These medicines may be affected by Ipratrin, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Ipratrin may be used with other medicines that relax the air passages for additional symptom relief, when prescribed by a doctor.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while using Ipratrin.

How to use Ipratrin

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

They may differ from the information contained in this leaflet.

If you are not sure how to use a nebuliser mask, or do not understand the instructions on the pack, ask your doctor or pharmacist for help.

You must make sure that a nebuliser mask is properly fitted to your or your child's nose and mouth before nebulising and inhaling Ipratrin.

Fit the nebuliser mask to your or your child's nose and mouth before nebulising and inhaling to prevent the mist from contacting your eyes.

If you find it difficult to breathe in and use your nebulising mask at the same time, talk to your doctor or pharmacist. They may be able to recommend another method.

Never let the Ipratrin solution or mist enter in or around your eyes. Should this occur, immediately flush your eyes with cold tap water for several minutes.

How much to use

The usual doses for adults and children are stated below.

Adults

- 1 to 2 ampoules (250 mcg to 500 mcg) of Ipratrin uni-dose 250 mcg/1 mL, or
- 1 ampoule (500 mcg) of Ipratrin Adult uni-dose 500 mcg/1 mL

diluted to 2 or 3 mL with normal saline, and nebulised until the entire volume of solution is inhaled, four times a day.

Depending on your condition and specific needs, your doctor may advise you to take a different dose.

Children

- 1 ampoule (250 mcg) of Ipratrin uni-dose 250 mcg/1 mL, diluted to 2 or 3 mL with normal saline and nebulised until the entire

volume of solution is inhaled, four times a day.

Depending on your child's condition and specific needs, your doctor may advise you to give a different dose.

Use only Ipratrin uni-dose 250 mcg/1 mL, unless advised otherwise by your doctor.

Only the lower strength of Ipratrin is suitable for children, as each ampoule contains the smaller dose recommended for children.

How to use it

The liquid in Ipratrin ampoules is for inhalation only. It must not be swallowed or injected.

Diluted solutions should be freshly prepared before use.

- 1. Before you use Ipratrin, prepare the nebuliser equipment for use according to the manufacturer's instructions and your doctor's advice.**
- 2. Carefully tear a new ampoule from the strip. Never use one that is already open.**
- 3. Open the ampoule by holding it upright and twisting off the top portion. Use the solution as soon as you open the ampoule.**
- 4. Place the open end of the ampoule well into the nebuliser bowl and squeeze it slowly until all the liquid has been emptied into the nebuliser bowl.**
- 5. If your doctor has told you to dilute Ipratrin, do this just before use with 2 to 3 mL of normal saline only.**
- 6. Assemble the nebuliser and inhale Ipratrin as directed.**
- 7. Make sure your nebuliser mask is properly fitted over your mouth and nose.**
This will reduce the chance of mist getting into your eyes.
- 8. After use, discard any liquid remaining in the nebuliser**

bowl or ampoule and clean the nebuliser as recommended.

When to use it

Use your medicine at about the same time each day.

Using it at the same time each day will have the best effect. It will also help you remember when to use it.

How long to use it for

Continue using Ipratrin for as long as your doctor tells you.

Ipratrin helps control your condition, but does not cure it. It is important to keep using it even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and have your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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.

If you take too much (overdose)

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

You may need urgent medical attention.

Symptoms of overdose may include:

- fast or irregular heart beat

- dry mouth
- blurred vision.

While you are using Ipratrin

Things you must do

Stop using Ipratrin and tell your doctor immediately if you get sudden tightness of chest, coughing, wheezing or breathlessness immediately after using Ipratrin.

These may be signs of a condition known as bronchospasm.

If you have an Asthma Action Plan that you have agreed to with your doctor, follow it closely at all times.

If you find that the usual dose of Ipratrin is not giving as much relief as before, or you need to use it more often, contact your doctor so that your condition can be checked.

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

Continue using Ipratrin for as long as your doctor or pharmacist tells you.

Visit your doctor regularly to check on your asthma condition.

Contact your doctor immediately if you experience irritation or a feeling of having something in the eye or any disturbances with your sight (blurred vision, visual halos or coloured images) together with red eyes, during or after using Ipratrin.

This may mean that you have developed a serious eye condition called narrow angle glaucoma. This can happen if the mist gets in your eyes.

Always use a new ampoule.

Used or left over solution may become contaminated as Ipratrin does not contain a preservative.

If your doctor has told you to dilute Ipratrin, do this with

normal saline only and immediately before use.

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

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

If you plan to have surgery, tell your surgeon or anaesthetist that you are using Ipratrin.

It may affect other medicines during surgery.

If you become pregnant while using this medicine, tell your doctor or pharmacist immediately.

Things you must not do

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

Do not give this medicine 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.

Do not stop using Ipratrin or lower the dosage, without checking with your doctor or pharmacist.

Do not allow the Ipratrin Uni-Dose mist to enter the eyes.

Do not swallow or inject the liquid.

Ipratrin is intended for inhalation with a suitable nebulising machine.

Things to be careful of

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

Ipratrin may cause dizziness and blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when performing physical activities.

Side effects

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

Ipratrin helps most people with asthma or chronic obstructive bronchitis, but may have unwanted side effects in a few people.

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

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

You may not experience any of them.

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

If you get any side effects, do not stop using Ipratrin without first talking to your doctor or pharmacist.

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

- headache
- dizziness
- dry or sore mouth
- throat irritation
- cough
- nausea, vomiting
- change in bowel movements (e.g. constipation, diarrhoea, wind, indigestion, reflux (an unusual backflow of fluid))

These are the more common side effects of Ipratrin. Most of these are mild and short lived.

Tell your doctor as soon as possible if you experience difficulty passing urine.

This is a serious side effect that may require medical attention.

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

- difficulty breathing or worsening of your breathing problems

- spasm of the muscles around the voice box, causing choking
- swelling of the throat
- fast or irregular heart beat, also called palpitations
- pounding heart beat
- allergic reaction (shortness of breath, wheezing or troubled breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin)
- irritation or a feeling of having something in the eye, red eyes, dilated pupils, blurred vision, visual halos or coloured images

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

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

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

After using Ipratrin

Storage

Keep Ipratrin 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.

Keep the solution in the ampoules until it is time to use them.

If you remove the solution from the ampoules it may not keep well.

Discard any liquid left in opened ampoules or in the nebuliser bowl.

Keep your ampoules in a cool dry place where the temperature stays below 25°C.

Keep the ampoules away from light.

Do not store Ipratrin or any other medicine in the bathroom or near a sink. Do not leave Ipratrin in the car or on window sills.

Heat, light and dampness can destroy the medicine.

Disposal

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

Product description

What it looks like

Ipratrin is available in 2 strengths:

- Ipratrin uni-dose 250 mcg/1 mL
- Ipratrin Adult uni-dose 500 mcg/1 mL.

Both strengths of Ipratrin come in plastic single-use ampoules containing a clear and colourless solution.

Each ampoule contains 1 mL of solution. Each pack contains 30 ampoules, arranged as 3 individually foil wrapped strips of 10 ampoules.

Ingredients

The active ingredient in Ipratrin is ipratropium bromide (anhydrous).

Each ampoule of Ipratrin uni-dose contains 261 mcg of ipratropium bromide [equivalent to 250 mcg of ipratropium bromide (anhydrous)].

Each ampoule of Ipratrin Adult uni-dose contains 522 mcg of ipratropium bromide [equivalent to 500 mcg of ipratropium bromide (anhydrous)].

Ipratrin uni-dose and Ipratrin Adult uni-dose also contains the following inactive ingredients:

- sodium chloride
- hydrochloric acid
- purified water.

Ipratrin uni-dose and Ipratrin Adult uni-dose are preservative free

Supplier

Ipratrin uni-dose and Ipratrin Adult uni-dose are supplied by:

Alphapharm Pty Limited

Level 1, 30 The Bond
30 Hickson Road
Millers Point NSW 2000
www.mylan.com.au.

Australian registration numbers:

Ipratrin uni-dose 250 mcg/1 mL –
AUST R 58164

Ipratrin Adult uni-dose 500 mcg/1
mL – AUST R 62144

® Ipratrin is a registered trademark.

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Directions for use

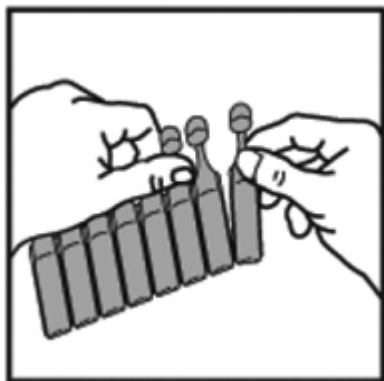
Ipratrin is intended for inhalation
with suitable nebulising equipment
and must not be swallowed.

Diluted solutions should be freshly
prepared before use.

At the end of inhalation, leftover
solution from nebuliser bowl should
be discarded.

Take the following steps in using
Ipratrin and if you have any
problems, ask your doctor or
pharmacist for assistance.

1. Get your nebuliser ready by
following the manufacturer's
instructions and advice of your
doctor.
2. Carefully tear a new vial from
the strip. Never use one that had
been opened already.



3. Open the vial by twisting off the
top, always taking care to hold it
in an upright position.



4. Squeeze the contents of the vial
into the nebulise bowl. If
dilution is necessary this should
be carried out using normal
saline and as instructed by your
doctor.
5. Assemble the nebuliser and take
the medicine or give it to your
child as directed by your doctor.



6. After nebulisation follow the
manufacturer's instructions
about cleaning your nebuliser.