

AERON 250/500

ipratropium bromide monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AERON.

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 or pharmacist has weighed the risks of you using AERON against the benefits it is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What AERON is used for

This medicine 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.

AERON contains the active ingredient ipratropium bromide

monohydrate. It belongs to a group of medicines called anticholinergic bronchodilators.

AERON 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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you use AERON

When you must not use it

Do not use AERON if you have an allergy to:

- any medicine containing ipratropium bromide monohydrate or any other medicines used to treat breathing problems
- any of the ingredients listed at the end of this leaflet
- any other similar medicines which contain atropine or medicines like atropine
- 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 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 taking 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:

- glaucoma (high pressure in the eye)
- difficulty or pain when passing urine
- constipation
- cystic fibrosis
- hyper reactive airway

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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 taking AERON.

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 and AERON may interfere with each other. These include:

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

These medicines may be affected by AERON 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 may prescribe AERON with other medicines that relax the air passages for additional symptom relief.

Check with your doctor or pharmacist before mixing other nebuliser solutions with AERON. Some nebulised medicines may not mix well with AERON and may need to be nebulised separately.

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

How to use AERON

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

They may differ from the information contained in this leaflet.

AERON 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 the nebuliser bowl should be discarded.

AERON should not be used if the bottle has been opened for more than 28 days.

After this period, a new AERON ampoule should be used.

If you have any problems with the following steps, ask your doctor or pharmacist for assistance:

1. Get your nebuliser ready by following the manufacturer's instructions and the advice of your doctor.
2. Twist an ampoule downwards to remove it from the strip.
3. Flick the ampoule so the solution flows to the bottom.
4. Hold the base of the ampoule and break the seal with a quick twisting action. Snap off the top.
5. Squeeze the contents of the ampoule into the nebuliser bowl.
6. If dilution is necessary, this should be carried out using normal saline, and as instructed by your doctor.
7. Assemble the nebuliser and use it as directed by your doctor.
8. After nebulisation follow the manufacturer's instructions about cleaning your nebuliser.

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

Children should only use AERON on medical advice and with the help of an adult.

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

Should the mist contact the eyes, immediately flush your eyes with cold tap water for several minutes.

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.

How much to use

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

When to use it

If your doctor has advised you to use AERON regularly, use your medicine at about the same time each day.

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

How long to use it

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine 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 take your next dose when you are meant to.

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

Do not take 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 take your medicine, ask your pharmacist for some hints.

If you take 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 AERON. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- fast or irregular heartbeat
- dry mouth
- blurred vision

While you are using AERON

Things you must do

If you get sudden tightness of the chest, coughing, wheezing or breathlessness immediately after using AERON, stop using AERON and tell your doctor immediately.

These may be signs of a condition called bronchospasm.

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

If you find that the usual dose of AERON 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 AERON for as long as your doctor or pharmacist tells you.

Contact your doctor immediately if your breathing suddenly becomes more difficult after using AERON.

This may be a sign of an allergic reaction.

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 AERON.

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

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

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

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

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Things you must not do

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

Do not allow the AERON solution to enter the eyes.

Do not take AERON 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 taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

This medicine 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 AERON.

This medicine helps most people with asthma or chronic obstructive bronchitis, but it 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 attention if you get some of the side effects.

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 you get any side effects, do not stop using AERON 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
- a change in bowel movements, e.g. constipation, diarrhoea, wind, indigestion, reflux (an unusual backflow of fluid)

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 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 your nearest hospital:

- difficulty breathing or worsening of your breathing problems
- swelling of the throat
- fast or irregular heartbeat, also called palpitations
- pounding heartbeat
- 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 that is making you feel unwell.

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

After using AERON

Storage

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

Do not store AERON 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 taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

AERON inhalation is a clear colourless solution essentially free from foreign particles. It comes in packs of 30 ampoules containing 1 mL of solution.

AERON comes in two strengths, 250 and 500 micrograms.

Ingredients

AERON contains either 216 micrograms per mL of ipratropium bromide monohydrate (equivalent to 250 micrograms per mL of ipratropium bromide) or 522 micrograms per mL of ipratropium bromide monohydrate (equivalent to 500 micrograms per mL of ipratropium bromide) as the active ingredient.

The solutions also contains the following inactive ingredients:

- hydrochloric acid
- sodium chloride
- water for injections

Distributor

AERON is distributed in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

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