Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Atrovent MDI?

Atrovent metered dose inhaler (Atrovent MDI) contains the active ingredient ipratropium bromide monohydrate. Atrovent MDI is used to make breathing easier for people with asthma or chronic obstructive pulmonary disease (COPD).

For more information, see Section <u>1. Why am I using</u> <u>Atrovent MDI?</u> in the full CMI.

2. What should I know before I use Atrovent MDI?

Do not use if you have ever had an allergic reaction to ipratropium, atropine or any medicines like atropine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know</u> <u>before I use Atrovent MDI?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Atrovent MDI and affect how it works.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I use Atrovent MDI?

Inhale each puff through the mouth. The usual doses are:

- <u>Adults</u>: 2 to 4 puffs, three to four times daily (at regular intervals), up to a maximum of 16 puffs a day
- <u>Children 6 to 12 years</u>: 1 to 2 puffs, three to four times daily (at regular intervals), up to a maximum of 8 puffs a day
- <u>Children under 6 years</u>: 1 puff, three times daily (at regular intervals)

More instructions can be found in Section <u>4. How do I</u> <u>use Atrovent MDI?</u> in the full CMI.

5. What should I know while using Atrovent MDI?

Things you should do	 Stop using Atrovent MDI and tell your doctor

	 immediately if you get sudden chest tightness, coughing, wheezing or breathlessness immediately after using Atrovent MDI. Tell your doctor immediately if you experience irritation of the eye or any disturbances with your sight together with red eyes. Remind any doctor, dentist or pharmacist you visit that you are using Atrovent MDI.
Things you should not do	 Do not stop using Atrovent MDI, or lower the dosage, without checking with your doctor or pharmacist. Do not allow the spray from Atrovent MDI to enter the eyes.
Driving or using machines	 Be careful driving or operating machinery until you know how Atrovent MDI affects you.

	 Atrovent MDI may cause dizziness and blurred vision in some people.
Looking after your medicine	 Clean and dry your mouthpiece at least once a week.
	 Keep your inhaler in a cool dry place (below 25°C) and keep out of reach of children. Do not puncture the container or throw it into a fire.

For more information, see Section <u>5. What should I know</u> while using Atrovent MDI? in the full CMI.

6. Are there any side effects?

Common but usually mild potential side effects include headache, dizziness, throat irritation, cough, dry mouth, nausea and digestion-related issues (e.g. constipation, diarrhoea, indigestion, reflux and wind).

Serious potential side effects that require medical attention include allergic reaction, difficulty in breathing, heartbeat changes, eye irritation or vision changes and difficulty in passing urine.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

ATROVENT METERED DOSE INHALER CMI0088-10

Atrovent[®] Metered Dose Inhaler

Active ingredient: ipratropium bromide monohydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Atrovent MDI. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Atrovent MDI.

Where to find information in this leaflet:

- 1. Why am I using Atrovent MDI?
- 2. What should I know before I use Atrovent MDI?
- 3. What if I am taking other medicines?
- 4. How do I use Atrovent MDI?
- 5. What should I know while using Atrovent MDI?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Atrovent MDI?

Atrovent metered dose inhaler (Atrovent MDI) contains the active ingredient ipratropium bromide monohydrate. Atrovent MDI is a type of bronchodilator, which are medicines that help to open up the airways.

Atrovent MDI is used to make breathing easier for people with asthma or chronic obstructive pulmonary disease (COPD).

Asthma is a disease where the lining of the lungs become inflamed (red and swollen), making it difficult to breathe.

COPD (which includes chronic bronchitis and emphysema) is a long-term, serious lung condition. You may have difficulty breathing (shortness of breath or wheezing), cough, tightness in your chest or coughing up phlegm.

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

2. What should I know before I use Atrovent MDI?

Warnings

Do not use Atrovent MDI if:

- You are allergic to ipratropium, or any of the ingredients listed at the end of this leaflet.
- You are allergic to atropine or medicines like atropine.

Check with 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 (a serious condition that affects the lungs and digestive system)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, intend to become pregnant, are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

Alcohol content

Atrovent MDI contains about 8 mg of alcohol in each puff. The amount in each puff is equal to less than 1 ml beer or

1 ml wine. The small amount of alcohol in Atrovent MDI will not have any noticeable effects.

3. What if I am taking other medicines?

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

Some medicines may be affected by Atrovent MDI or may interfere with how Atrovent MDI works. These include:

- Medicines used to treat heart problems such as adrenaline.
- Medicines used to treat asthma or COPD such as theophylline, salbutamol and tiotropium.

You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Atrovent MDI.

4. How do I use Atrovent MDI?

How much to use

The recommended doses are:

- <u>Adults</u>: 2 to 4 puffs, three to four times daily (at regular intervals), up to a maximum of 16 puffs a day.
- <u>Children 6 to 12 years</u>: 1 to 2 puffs, three to four times daily (at regular intervals), up to a maximum of 8 puffs a day.

• <u>Children under 6 years:</u> 1 puff, three times daily (at regular intervals).

Your doctor may advise you to use a different dose, depending on your condition and specific needs.

Follow the instructions provided by your doctor or pharmacist and use Atrovent MDI until your doctor tells you to stop.

When to use Atrovent MDI

Use Atrovent MDI at about the same time each day.

How to use Atrovent MDI

Detailed instructions (with diagrams) on how to use Atrovent MDI is available online:

https://medsinfo.com.au/media/byiatrcf

This Instructions for Use leaflet is also enclosed in your carton.

- Inhale each puff properly through the mouth.
- Ask your doctor or pharmacist for help if:
 - you are not sure how to use the inhaler
 - you find it difficult to breathe in and use your inhaler at the same time. Your doctor or pharmacist may recommend another method, such as using a spacer with the inhaler.
- Children should only use their inhaler on medical advice and with the help of an adult.

If you forget to use Atrovent MDI

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 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.

Ask your doctor or pharmacist if you are not sure what to do.

If you use too much Atrovent MDI

If you think that you have used too much Atrovent MDI, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include:

• a fast or irregular heartbeat

- dry mouth
- blurred vision.

5. What should I know while using Atrovent MDI?

Things you should do

- Stop using Atrovent MDI and contact your doctor immediately if you get sudden tightness of the chest, coughing, wheezing or breathlessness immediately after using Atrovent MDI. These may be signs of a condition called bronchospasm.
- 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 Atrovent MDI. This may mean that you have developed a serious eye condition called narrow-angle glaucoma. This can happen if the spray gets in your eyes.
- Tell your doctor immediately if you become pregnant
- If you have an Asthma or COPD Action Plan that you have agreed with your doctor, follow it closely at all times.
- If you find that the usual dose of Atrovent MDI 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.
- Remind any doctor, dentist or pharmacist you visit that you are using Atrovent MDI.

- If you plan to have surgery, tell the surgeon or anaesthetist that you are using Atrovent MDI. It may affect other medicines used during surgery.
- Keep all of your doctor's appointments so that your progress can be checked.
- Keep your Atrovent MDI with you at all times.

Things you should not do

- Do not take any other medicines for your breathing problems without checking with your doctor.
- Do not give Atrovent MDI to anyone else, even if they have the same condition as you.
- Do not use Atrovent MDI to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop using Atrovent MDI or lower the dosage without checking with your doctor or pharmacist.
- Do not allow the Atrovent MDI spray to enter your eyes.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Atrovent MDI affects you.

Atrovent MDI 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.

Looking after your medicine

- Clean and dry your mouthpiece at least once a week. Follow the cleaning directions in the Instructions for Use leaflet (the leaflet is enclosed in the carton and is also available online via the link in Section <u>4. How do I use Atrovent MDI?</u>). It is important to keep the mouthpiece of your inhaler clean and dry. It may not work as well if it gets dirty.
- Keep your inhaler in a cool dry place where the temperature stays below 25°C.
- Do not store it:
 - in the bathroom or near a sink, or
 - in the car or on window sills.
- Keep Atrovent MDI where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Do not puncture the container or throw it into a fire.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
 Brain and nerves: headache dizziness Mouth, throat and airways: 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.
 dry mouth sore or swollen mouth throat irritation cough Gut and digestion: 	
 nausea or vomiting change in bowel movements (e.g. constipation, diarrhoea) wind indigestion reflux (an unusual backflow of fluid) 	

Serious side effects

Serious side effects	What to do
Signs of an allergic reaction:	Call your doctor straight away, or go straight
 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 Mouth, throat and airways: difficulty breathing or worsening of your breathing problems spasm of the muscles around the voice box, causing choking swelling of the throat Heart: fast or irregular heartbeat pounding heartbeat Eyes: 	to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
 irritation or a feeling of having something in the eye 	
 dilated pupils blurred vision 	
 visual halos or coloured images 	
Bladder:	
 difficulty passing urine 	

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Atrovent MDI contains

Each dose (puff) of Atrovent MDI contains:

Active ingredient (main ingredient)	ipratropium bromide monohydrate (21 micrograms)
Other ingredients (inactive ingredients)	citric acid purified water absolute ethanol norflurane
Potential allergens	alcohol

Do not take this medicine if you are allergic to any of these ingredients.

Atrovent MDI does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What Atrovent MDI looks like

Atrovent MDI (AUST R 91129) is supplied in a can with a mouthpiece and it contains 200 puffs.

Who distributes Atrovent MDI

Atrovent MDI is distributed in Australia by: Boehringer Ingelheim Pty Limited ABN 52 000 452 308 Sydney NSW www.boehringer-ingelheim.com.au

This leaflet was prepared in August 2022.

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