APO-Mebeverine

Consumer Medicine Information (CMI) summary

The full CMI 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 APO-Mebeverine?

APO-Mebeverine contains the active ingredient mebeverine hydrochloride. APO-Mebeverine is taken to relieve the symptoms of irritable bowel syndrome, which can include, abdominal pain and cramps, bowel spasm, diarrhoea and flatulence. For more information, see Section 1. Why am I using APO-Mebeverine? in the full CMI.

2. What should I know before I use APO-Mebeverine?

Do not use if you have ever had an allergic reaction to APO-Mebeverine 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 2. What should I know before I use Apo-Mebeverine? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Mebeverine and affect how it works.

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

4. How do I use APO-Mebeverine?

- Take APO-Mebeverine at about the same time each day. The usual dose is one tablet three times a day.
- Take APO-Mebeverine immediately before or during a meal. Swallow the tablets with a glass of water.

More instructions can be found in Section 4. How do I use APO-Mebeverine? in the full CMI.

5. What should I know while using APO-Mebeverine?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are taking APO-Mebeverine. If you become pregnant while you are taking APO-Mebeverine, tell your doctor immediately.
Things you should not do	 Do not take APO-Mebeverine to treat any other complaints unless your doctor or pharmacist tells you to. Do not give APO-Mebeverine to anyone else, even if they have the same condition as you. Do not stop taking APO-Mebeverine, or lower the dosage, without checking with your doctor.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how APO-Mebeverine affects you.
Looking after your medicine	 Keep your tablets in the pack until it is time to take them. Keep APO-Mebeverine in a cool, dry place where the temperature stays below 25°C. Keep it where young children cannot reach it.

For more information, see Section 5. What should I know while using APO-Mebeverine? in the full CMI.

6. Are there any side effects?

Speak to your doctor if you have any of these less serious side effects and they worry you: indigestion or heartburn, constipation, dizziness, headache, tiredness, difficulty sleeping, loss of appetite. Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects: swelling of the face, lips or tongue, difficulty swallowing or breathing.

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

APO-Mebeverine

Active ingredient(s): mebeverine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about taking APO-Mebeverine. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking APO-Mebeverine.

Where to find information in this leaflet:

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

1. Why am I using APO-Mebeverine?

APO-Mebeverine contains the active ingredient mebeverine hydrochloride. APO-Mebeverine belongs to a group of medicines called known as antispasmodic agents.

APO-Mebeverine works by relaxing the muscles in the gut, thereby relieving the symptoms of irritable bowel syndrome.

APO-Mebeverine is taken to relieve the symptoms of irritable bowel syndrome, which can include, abdominal pain and cramps, bowel spasm, diarrhoea and flatulence.

2. What should I know before I use APO-Mebeverine?

Warnings

Do not use APO-Mebeverine if:

you are allergic to mebeverine hydrochloride, or any
of the ingredients listed at the end of this leaflet.
 Always check the ingredients to make sure you can
take this medicine.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Check with your doctor if you:

- have any of the following medical conditions:
 - angina or other heart conditions
 - liver problems

- kidney problems
- lactose intolerance
- take any medicines for any other condition

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</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

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

4. How do I use APO-Mebeverine?

How much to take

- The usual dose is one tablet three times a day.
- Follow the instructions provided and continue taking APO-Mebeverine until your doctor tells you to stop.
- It is important to keep taking your medicine even if you feel well.

When to take APO-Mebeverine

- Take APO-Mebeverine immediately before or during a meal
- Take APO-Mebeverine 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 to take APO-Mebeverine

• Swallow the tablets with a glass of water.

If you forget to take APO-Mebeverine

APO-Mebeverine should be taken at the same time each day. If you miss your dose at the usual time, take it as

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

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

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

- This may increase the chance of getting an unwanted side effect.
- If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

If you use too much APO-Mebeverine

If you think that you have used too much APO-Mebeverine, 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.

5. What should I know while using APO-Mebeverine?

Things you should do

Call your doctor straight away if you:

 become pregnant while you are taking APO-Mebeverine

If you are going to have surgery, tell the surgeon that you are taking APO-Mebeverine.

Remind any doctor, dentist or pharmacist you visit that you are taking APO-Mebeverine.

Things you should not do

- Do not take APO-Mebeverine to treat any other complaints unless your doctor or pharmacist tells you
- Do not give APO-Mebeverine to anyone else, even if they have the same condition as you.
- Do not stop taking APO-Mebeverine, or lower the dosage, without checking with your doctor

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-Mebeverine affects you.

Looking after your medicine

 Keep your tablets in the pack until it is time to take them.

- If you take the tablets out of the box or the blister pack
- they may not keep well.
- Keep the medicine in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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.

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.

Less serious side effects

Less serious side effects	What to do
The below list includes the more common side effects of your medicine. They are usually mild and short-lived. • indigestion or heartburn • constipation • dizziness • headache • tiredness • difficulty sleeping • loss of appetite	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 These side effects are rare. swelling of the face, lips or tongue Difficulty swallowing or breathing 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of

these serious
side effects.

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 www.tga.gov.au/reporting-problems. 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 APO-Mebeverine contains

Active ingredient (main ingredient)	135mg mebeverine hydrochloride
Other ingredients	Lactose monohydrate
(inactive ingredients)	Sodium starch glycolate type A
	Povidone
	Purified talc
	Magnesium stearate
	OPADRY complete film coating system 03F58763 White.
Potential allergens	This medicine contain sugars as lactose.

This medicine does not contain gluten.

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

What APO-Mebeverine looks like

APO-Mebeverine is white, round biconvex film-coated tablets and plain on both sides. [Aust R 288817].

Who distributes APO-Mebeverine

Arrotex Pharmaceuticals Pty Ltd 15 – 17 Chapel Street Cremorne, VIC 3121

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