

APO-Metoclopramide

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-Metoclopramide?

APO-Metoclopramide contains the active ingredient metoclopramide hydrochloride (as monohydrate). APO-Metoclopramide is used to treat nausea and vomiting caused by infectious diseases, kidney disease, childbirth, other medications, cancer, or following surgery, chemotherapy, or radiation treatment.

For more information, see Section [1. Why am I using APO-Metoclopramide?](#) in the full CMI.

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

Do not use it if you have ever had an allergic reaction to APO-Metoclopramide 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-Metoclopramide?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Metoclopramide 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-Metoclopramide?

- APO-Metoclopramide should be used at about same time each day.
- Taking it at same time each day will have the best effect. It will also help you remember when to take it.
- Take the medicine 30 minutes before a meal.

More instructions can be found in Section [4. How do I use APO-Metoclopramide?](#) in the full CMI.

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

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using APO-Metoclopramide.• Call your doctor if you experience vomiting or nausea or if it persists.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly if the symptoms stop.• Do not take this medicine to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• APO-Metoclopramide may cause dizziness, light-headedness, tiredness, or drowsiness in some people.• If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol when you are taking this medicine.• If you drink alcohol, it may make you sleepy.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in its original packaging until it is time to take it.• If you take your medicine out of its original packaging it may not keep well.• Keep your medicine in a cool dry place where the temperature is will stay below 25OC.

For more information, see Section [5. What should I know while using APO-Metoclopramide?](#) in the full CMI.

6. Are there any side effects?

Common side effects include drowsiness, tiredness, restlessness dizziness or headache, bowel irregularities, insomnia, anxiety and agitation.

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-METOCLOPRAMIDE

Active ingredient(s): *metoclopramide hydrochloride (as monohydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Metoclopramide. **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 APO-Metoclopramide.**

Where to find information in this leaflet:

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

1. Why am I using APO-Metoclopramide?

APO-Metoclopramide contains the active ingredient metoclopramide hydrochloride (as monohydrate). APO-Metoclopramide works by blocking the action of a chemical in the brain which causes nausea and vomiting. It also acts in the stomach and upper intestine to increase muscle contraction.

APO-Metoclopramide is used in adults over 20 years and old:

- to treat nausea and vomiting caused by infectious diseases, kidney disease, childbirth, other medications, cancer, or following surgery, chemotherapy, or radiation treatment.
- To activate stomach contractions in conditions where there is a need to encourage normal passage of food through the stomach and intestines.
- With X-rays to help diagnose problems of the stomach and/or intestines
- To help with passing tubes into the intestine.

In young adults between 15 to 20 years old this medicine is used when other therapies haven't worked to:

- Treat severe vomiting of known cause or following chemotherapy or radiation treatment.
- Help with passage tubes into the intestines.

These tablets should not be used for children under 15 years of age.

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

Your doctor may have prescribed this medicine for another reason.

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

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

Warnings

Do not use APO-Metoclopramide if:

- you are allergic to metoclopramide hydrochloride (as monohydrate), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Some of the symptoms of 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 give this medicine to a child under the age of 15 years.**
- Safety and effectiveness in children younger than 15 years have not been established.

Do not take this medicine if you take other medication such as antipsychotic/neuroleptic medication and certain antidepressants that can cause movement disorders (extrapyramidal reactions).

Check with your doctor if you:

- have any other medical conditions like Parkinson's disease, liver or kidney problems, high blood pressure, depression.
- other medical conditions as listed below:
- Active bleeding from the stomach and/or digestive tract
- Blockage of the stomach and/or digestive track
- Phaeochromocytoma (an adrenaline – producing tumor of the adrenal gland)
- Epilepsy (fits or seizures)
- Porphyria (a rare blood pigment disorder)
- take any medicine for any other condition.
- Do not take this medicine if you take other medication such as antipsychotic/neuroleptic medication and

certain antidepressants that can cause movement disorders (extrapyramidal reactions).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. 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.

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

- Tranquilizers or anti-anxiety medications
- Strong pain relievers (e.g., codeine or morphine)
- Phenothiazines, used to treat mental and emotional disorders.
- Sedatives or sleeping medications.
- Atropine-like medications (e.g., some cold preparations, relief of stomach cramps or spasms, travel sickness)
- Tetracycline antibiotics
- Paracetamol
- Levodopa
- Digoxin
- Cyclosporin is used to help prevent organ transplant rejection or to treat certain problem with the immune system.

These medicines may be affected by metoclopramide or may affect how well it works. You may need different amounts of your medicine, 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 APO-Metoclopramide.

4. How do I use APO-Metoclopramide?

How much to take / use

- Follow carefully all directions given to you by your doctor.
- The instructions may be different to the information in this leaflet.
- If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

When to take / use APO-Metoclopramide

- APO-Metoclopramide should be used at about the same time each day.
- Taking it at same time each day will have the best effect. It will also help you remember when to take it.
- Take the medicine 30 minutes before meals.

If you forget to use APO-Metoclopramide

APO-Metoclopramide should be used regularly 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 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 use too much APO-Metoclopramide

If you think that you have used too much [medicine name], 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 drowsiness, confusion, tremor, twitching, or uncontrolled spasm of muscles, feelings of anxiety, or restlessness, headache, vertigo, nausea, vomiting, constipation, weakness, low blood pressure and dry mouth.

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

Things you should do

Call your doctor straight away if you:

- Experience vomiting or nausea or if it persists.
- If you are about to be started on any new medicine, remind your doctor and pharmacists that you are taking this medication.
- 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 or start to breastfeed while taking this medicine, tell your doctor immediately.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.
- It may interfere with the results of some tests.
- Keep all your doctor's appointments so that your progress can be checked.
- Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Remind any doctor, dentist, or pharmacist you visit that you are using APO-Metoclopramide.

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.
- Do not take this medicine 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.

Driving or using machines

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

APO-Metoclopramide may cause dizziness, light-headedness, tiredness, or drowsiness in some people.

If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol when you are taking this medicine.

If you drink alcohol, it may make you sleepy.

Looking after your medicine

- Keep your medicine in its original packaging until it is time to take it.
- If you take your medicine out of its original packaging it may not be kept well.
- Keep your medicine in a cool dry place where the temperature will stay 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 windowsills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

When to discard your medicine

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.

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
<ul style="list-style-type: none"> • Drowsiness, tiredness • Restlessness • Dizziness or headache • Bowel irregularities • Insomnia • Anxiety • Agitation 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Uncontrolled or repeated movements, e.g., sucking or smacking of the lips, darting of the tongue, chewing movements, uncontrolled movement of the arms or legs-this may be a sign of tardive dyskinesia, a movement disorder which can be potentially irreversible. • Fast heartbeat • Increasing number of infections • Elevated temperature with no clear cause • Breast enlargement or milk secretions 	<p>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.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • Depression • Urinary incontinence and frequency 	

Very Serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> • sudden uncontrolled muscle spasm, stiffness of the arms or legs, muscle spasm of the face, locked jaw or upturned eyes • shuffling walk, slowing of all movement, muscle tremor • neuroleptic malignant syndrome, a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions • yellowing of the skin (jaundice) • symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat, or other parts of the body; rash, itching or hives on the skin 	<p>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.</p>

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

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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-Metoclopramide contains

Active ingredient (main ingredient)	Metoclopramide hydrochloride (as monohydrate)
Other ingredients (inactive ingredients)	Maize starch Pregelatinized maize starch Microcrystalline cellulose Colloidal anhydrous silica Stearic acid Hypromellose Macrogol 6000 Titanium dioxide Purified talc
Potential allergens	N/A

This medicine is gluten free , lactose free, sucrose free, tartrazine free and free of other azo dyes.

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

What APO-Metoclopramide looks like

10 mg tablets:

APO-Metoclopramide 10 mg tablets are white to off-white, circular, biconvex film-coated tablets with break line on both sides (Aust R 196502).

Available in blister packs of 25 and 100.

Not all strengths, pack types and/or pack sizes may be available.

Who distributes APO-Metoclopramide?

Arrotex Pharmaceuticals

15-17 Chapel Street

Cremorne VIC 3121

Australia

Tel: 1800 195 055

Web: www.arrotex.com.au

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