Consumer Medicine Information (CMI) summary

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

1. Why am I taking Maxolon?

Maxolon contains the active ingredient metoclopramide hydrochloride. Maxolon is used to manage nausea and vomiting. For more information, see Section <u>1. Why am I taking Maxolon?</u> in the full CMI.

2. What should I know before I take Maxolon?

Do not take if you have ever had an allergic reaction to 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 take Maxolon? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Maxolon 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 take Maxolon?

- <u>Adults 20 years and over:</u> take 1 tablet every 8 hours.
- <u>Adolescents: 15 to 19 years:</u> take ¹/₂ to 1 tablet every 8 hours.

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

5. What should I know while taking Maxolon?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are taking Maxolon. Tell your doctor if nausea and vomiting persist. Tell your doctor if you become pregnant while taking Maxolon. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Maxolon. 	
Things you should not do		
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how Maxolon affects you. Maxolon may cause dizziness, light-headedness, tiredness or drowsiness in some people. 	
Drinking alcohol	Drinking alcohol whilst taking Maxolon may make you sleepy.	
Looking after your medicine	Store below 30°C.	

For more information, see Section 5. What should I know while taking Maxolon? in the full CMI.

6. Are there any side effects?

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

Serious side effects include uncontrolled or repeated movements, (e.g., sucking or smacking of the lips, darting of the tongue, chewing movements, uncontrolled movements of the arms or legs), fast heartbeat, depression, or swelling of hands, ankles, or feet.

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.

Active ingredient: metoclopramide hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Maxolon. 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 Maxolon.

Where to find information in this leaflet:

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

1. Why am I taking Maxolon?

Maxolon contains the active ingredient metoclopramide hydrochloride. Maxolon 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 contractions.

Maxolon is used in adults 20 years and over to:

- treat nausea and vomiting caused by infectious diseases, migraine, kidney disease, childbirth, other medications, cancer, or following surgery, chemotherapy or radiation treatment.
- 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.
- help with passing tubes into the intestine.

Maxolon is used in young adults aged 15 – 19 years to:

- treat severe vomiting of known cause or following chemotherapy or radiation treatment.
- help with passing tubes into the intestine.

2. What should I know before I take Maxolon?

Warnings

Do not use Maxolon if you:

- are allergic to metoclopramide or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- have active bleeding from the stomach and/or digestive tract.
- have a blockage of the stomach and/or digestive tract.
- have had recent surgery of the stomach and/or digestive tract.
- have phaeochromocytoma (an adrenaline producing tumour of the adrenal gland).
- have epilepsy (fits or seizures)

• take other medication such as antipsychotic/ neuroleptic medication and certain antidepressants that can cause movement disorders.

Check with your doctor if you:

- have any other medical conditions including:
 - Parkinson's disease
 - o liver or kidney problems
 - high blood pressure
 - o asthma.
- 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. Are there any side effects</u>?

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.

Use in children

Do not give Maxolon to children less than 15 years old.

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 Maxolon may interfere with each other. These include:

- tranquilisers or anti-anxiety medications
- strong pain relievers (e.g., codeine or morphine)
- sedatives or sleeping medication
- atropine-like medications (e.g., some cold preparations, travel sickness medicines)
- tetracycline antibiotics, paracetamol, levodopa
- digoxin.

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

4. How do I take Maxolon?

How much to take

Follow the instructions provided and use Maxolon until your doctor tells you to stop.

Do not exceed the prescribed dose.

- Adults 20 years and over 1 tablet every 8 hours.
- <u>Adolescents: 15 to 19 years</u> ¹/₂ to 1 tablet every 8 hours.
- Swallow the tablets with a full glass of water.
- If required, the tablets can be broken in half (along the break-line).
- Take your tablet at least 30 minutes before meals.

If you are taking Maxolon before a diagnostic procedure your doctor will give you your dose.

This will usually be a single dose of 1-2 tablets depending on your age.

If you have significant kidney or liver impairment your doctor may prescribe a lower dose.

How long to take Maxolon

Your doctor will advise you how long to take Maxolon. The maximum recommended treatment duration is 5 days.

If you forget to take Maxolon

Maxolon should be taken regularly at the same time each day.

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.

If you take too much Maxolon

If you think that you have taken too much Maxolon, you may need urgent medical attention.

Symptoms of an overdose may include drowsiness, confusion, dizziness, headache, agitation, nausea, vomiting, constipation, tremor, twitching or uncontrolled spasm of muscles.

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 taking Maxolon?

Things you should do

Call your doctor if:

- nausea and vomiting persist.
- you become pregnant while taking Maxolon.

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

It may affect other medicines used during surgery.

Remind any doctor, dentist or you visit that you are taking Maxolon.

Things you should not do

- Do not use Maxolon to treat any other conditions unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition.

Driving or using machines

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

Maxolon 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.

Alcohol may make you sleepy.

Looking after your medicine

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

Store it in a cool dry place below 30 °C 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.

Getting rid of any unwanted medicine

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

Do not use Maxolon 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	What to do
 drowsiness, tiredness restlessness dizziness, headache. bowel irregularities insomnia anxiety agitation 	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
•	uncontrolled or repeated movements, e.g., sucking or smacking of the lips, darting of the tongue, chewing movements, uncontrolled movements of the arms or legs. This may be a sign of tardive dyskinesia, a movement disorder which can be potentially irreversible. fast heartbeat depression swelling of hands, ankles, or feet.	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.

Very serious side effects

Very serious side effects	What to do
 allergic reaction including fainting, swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing. sudden uncontrolled muscle spasm, stiffness of the arms or 	Call your doctor straight away, or go straight to the Emergency Department at

Very serious side effects	What to do
 legs, muscle spasm of the face, locked-jaw or upturned eyes depression 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 	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 <u>www.tga.gov.au/</u> <u>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 Maxolon contains

Active ingredient (main ingredient)	Metoclopramide hydrochloride
Other ingredients	Colloidal anhydrous silica
(inactive	Lactose
ingredients)	Magnesium stearate
	Maize starch
	Pregelatinised maize starch
Potential allergens	Lactose

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

What Maxolon looks like

Maxolon is a round white tablet marked with Maxolon on one side and a break line on the other side.

Registration number: AUST R 11153.

Who distributes Maxolon

iNova Pharmaceuticals (Australia) Pty Ltd

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

This leaflet was prepared in December 2023