

PRAMIN

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 PRAMIN?

PRAMIN contains the active ingredient metoclopramide hydrochloride. PRAMIN is used to manage nausea and vomiting.

For more information, see Section [1. Why am I taking PRAMIN?](#) in the full CMI.

2. What should I know before I take PRAMIN?

Do not take if you are allergic to medicines containing metoclopramide hydrochloride 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 PRAMIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PRAMIN 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 PRAMIN?

- Adults 20 years and over - 1 tablet every 8 hours.
- Adolescents: 15 to 19 years - ½ to 1 tablet every 8 hours.
- The dose varies with the age of the patient and reason for use. Children and adolescents are very sensitive to the effects of PRAMIN. Your doctor will normally start the treatment at the lower dose.

More instructions can be found in Section [4. How do I take PRAMIN?](#) in the full CMI.

5. What should I know while taking PRAMIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking PRAMIN.• Tell your doctor if nausea and vomiting persist.• Tell your doctor if you become pregnant while taking PRAMIN.• If you are going to have surgery, tell the surgeon or anaesthetist you are taking PRAMIN.
Things you should not do	<ul style="list-style-type: none">• Do not exceed the recommended dose.• Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how PRAMIN affects you.• PRAMIN may cause dizziness, light-headedness, tiredness or drowsiness in some people.
Drinking alcohol	<ul style="list-style-type: none">• Drinking alcohol whilst taking PRAMIN may make you sleepy.
Looking after your medicine	<ul style="list-style-type: none">• Store in a cool dry place where the temperature stays below 30°C.• Keep your tablets in the original container until it is time to take them.

For more information, see Section [5. What should I know while taking PRAMIN?](#) in the full CMI.

6. Are there any side effects?

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

Some of the more 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 or irregular heartbeat, depression, and 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.

PRAMIN

Active ingredient(s): *metoclopramide hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking PRAMIN. **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 PRAMIN.**

Where to find information in this leaflet:

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

1. Why am I taking PRAMIN?

PRAMIN contains the active ingredient metoclopramide hydrochloride. PRAMIN belongs to a group of medicines called anti-emetics and is thought to work by blocking the action of a chemical in the brain which causes nausea and vomiting. It also increases the muscle contractions in the stomach and upper intestine.

PRAMIN 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. E.g., certain stomach problems associated with diabetes.
- with X-rays to help diagnose problems of the stomach and/or intestines.
- help with passing tubes into the intestine.

PRAMIN is used in young adults and children over 1 year of age to:

- treat 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 PRAMIN?

Warnings

Do not take PRAMIN if you:

- are allergic to metoclopramide hydrochloride, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- wheezing or shortness of breath

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- rash, itching or hives on the skin

Always check the ingredients to make sure you can take 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 likely to cause extrapyramidal effects, such as antipsychotic/neuroleptic medication and certain antidepressants that can cause movement disorders. This reaction may include trembling and a sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body.

Check with your doctor if you:

- have any other medical conditions including:
 - Parkinson's disease - a condition affecting muscle control and movement
 - liver or kidney problems
 - high blood pressure
 - asthma
 - depression
 - breast cancer
- take any medicines for any other condition
- have allergies to any other medicines, foods, dyes or preservatives.

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell him/her before you start taking PRAMIN.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

Your doctor will discuss the risks and benefits of taking this medicine during pregnancy.

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

PRAMIN passes into breast milk and can affect the flow of your breast milk. Your doctor will discuss the risks and benefits of taking this medicine when breastfeeding.

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 PRAMIN may interfere with each other. These include:

- medicines used to help you sleep (tranquilisers) and/or to relieve anxiety
- pain relievers (e.g., paracetamol, codeine or morphine)
- sedatives or sleeping medication
- atropine-like medications (e.g., some cold preparations, travel sickness medicines, stomach cramp medicines)
- tetracycline antibiotics,
- levodopa, a medicine used in the treatment of Parkinson's disease
- digoxin, a medicine used to treat heart failure
- ciclosporin, a medicine used to help prevent organ transplant rejection
- monoamine oxidase inhibitors, a group of medicines used to treat depression
- certain medicines used to treat mental disorders, including lithium, thioridazine

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

4. How do I take PRAMIN?

How much to take

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

The dose of PRAMIN varies with the age of the patient and reason for use.

Do not exceed the prescribed dose.

- Adults 20 years and over - 1 tablet every 8 hours.
- Adolescents: 15 to 19 years - ½ to 1 tablet every 8 hours.
- The daily dosage of PRAMIN, especially for children and adolescents, should not normally exceed 0.5mg/kg bodyweight or 30 mg daily.

Children and adolescents are very sensitive to the effects of PRAMIN. Your doctor will normally start the treatment at the lower dose. Do not exceed the prescribed dose in these age groups.

If you are taking PRAMIN 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.

When to take PRAMIN

- PRAMIN is best taken 30 minutes before symptoms are likely to occur or 30 minutes before meals. Space the doses of PRAMIN evenly throughout your day.
- Your doctor may tell you to take PRAMIN only when required for each occasion of nausea and vomiting.

How to take PRAMIN

- Swallow the tablets with a full glass of water.
- The tablets can be broken in half (along the break-line).

How long to take PRAMIN

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

If you forget to take PRAMIN

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 the missed dose as soon as you remember, and then go back to taking your tablet as you would normally.

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 take too much PRAMIN

If you think that you or anyone else has taken too much PRAMIN, urgent medical attention may be needed.

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

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 PRAMIN?

Things you should do

Call your doctor if:

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

If you are going to have surgery, including dental surgery, tell the surgeon, anaesthetist or dentist that you are taking PRAMIN.

It may affect other medicines used during the surgery.

If you have any liver function tests or other tests, tell your doctor.

PRAMIN may affect the results of some tests.

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

Things you should not do

- **Do not use PRAMIN 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 as you.**

Driving or using machines

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

PRAMIN 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. Children should be careful when riding bicycles or climbing trees.

Drinking alcohol

Tell your doctor if you drink alcohol.

Combining PRAMIN and alcohol can make you sleepy.

Looking after your medicine

Keep your tablets in the original container until it is time to take them. If you take the tablets out of the original container they may not keep well.

PRAMIN should be stored 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.

Heat or dampness can destroy some medicines.

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 take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

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, fatigue • restlessness • dizziness, headache • bowel irregularities, diarrhoea, constipation • insomnia (trouble sleeping) • anxiety • agitation • restlessness • breast enlargement, unusual secretion of breast milk 	<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 movements of the arms or legs. This may be a sign of tardive dyskinesia, a movement disorder which can potentially be irreversible • fast or irregular heartbeat • depression • yellowing of the skin or eyes • swelling of hands, ankles or feet 	<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>

Very serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • allergic reaction including fainting, swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing, wheezing or shortness of breath • 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 	<p>Stop taking PRAMIN and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PRAMIN even if you do not think that it is connected with the medicine.

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.

If you are over 65 years of age, you may have an increased chance of getting side effects.

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. There is no evidence that PRAMIN is addictive.

What PRAMIN contains

Active ingredient (main ingredient)	metoclopramide hydrochloride 10mg (as hydrate)
Other ingredients (inactive ingredients)	lactose anhydrous pregelatinised maize starch microcrystalline cellulose colloidal anhydrous silica magnesium stearate
Potential allergens	lactose trace amounts of sulfites

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

What PRAMIN looks like

PRAMIN is a white, normal convex tablet marked "ME" over "10" on one side and "G" on the reverse (AUST R 364450).

Available in blister packs of 25 tablets.

Who distributes PRAMIN

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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