METOMAX®

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 taking METOMAX?

METOMAX contains the active ingredients metoclopramide hydrochloride (as monohydrate) and paracetamol. METOMAX is used for the relief of headache, nausea, and vomiting associated with migraine.

For more information, see Section 1. Why am I taking METOMAX? in the full CMI.

2. What should I know before I take METOMAX?

Do not take if you have ever had an allergic reaction to paracetamol and/or 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 METOMAX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with METOMAX 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 METOMAX?

- The initial dosage for adults is 1 to 2 capsules and then 1-2 capsules every 4 hours, as needed. Do not take more than 6 capsules in 24 hours, and do not take it for longer than 48 hours at a time unless advised to by a doctor.
- METOMAX should be taken at the first sign of a migraine attack.
- Swallow the capsule with a glass of water.

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

5. What should I know while using METOMAX?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using METOMAX. • Tell your doctor or pharmacist if nausea, vomiting or headache persists.
Things you should not do	• Do not give this medicine to anyone else, even if they have similar symptoms. • Do not take METOMAX to treat any other complaints unless your doctor or pharmacist tells you to. • Do not take METOMAX with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.
Driving or using machines	• Be careful before you drive or use any machines or tools

	until you know how METOMAX affects you.
Drinking alcohol	• Avoid drinking alcohol while taking METOMAX.
Looking after your medicine	• Keep your METOMAX capsules in the original packaging, in a cool dry place, away from moisture or heat where the temperature stays below 25°C.

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

6. Are there any side effects?

Very common side effects of METOMAX include restlessness, drowsiness, fatigue, and lethargy. Common side effects include insomnia, headache, dizziness, nausea, or bowel upsets. Serious side effects of METOMAX include unusual changes in mood, different types of muscle spasms or rigidity, an allergic reaction, difficulty breathing, severe drowsiness/fatigue, or a bluish discolouration of the skin.
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.

METOMAX®

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using METOMAX. **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 METOMAX.**

Where to find information in this leaflet:

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

1. Why am I taking METOMAX?

METOMAX contains the active ingredients paracetamol and metoclopramide hydrochloride (as monohydrate). METOMAX is used for the relief of headache, nausea and vomiting associated with migraine.

Metoclopramide helps control nausea and vomiting caused by migraine and other illnesses. It 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.

Paracetamol is an analgesic. It provides effective temporary relief from pain (such as headache).

2. What should I know before I take METOMAX?

Warnings

Do not take METOMAX if:

- you have any of the following health conditions:
  - porphyria (causing pain, nausea and vomiting)
  - pain in the stomach, chest, legs or back
  - bleeding from the stomach and/or digestive tract
  - intestinal blockage
  - recent surgery on the stomach and/or digestive tract
  - phaeochromocytoma (a rare tumour of the adrenal gland)
  - epilepsy (fits).
- you are allergic to metoclopramide, paracetamol or any of the ingredients listed at the end of this leaflet. Some symptoms of an allergic reaction may include;
  - shortness of breath
  - wheezing or difficulty in breathing

- swelling of the face, lips, tongue, or any other parts of the body
- rash, itching or hives on the skin.

- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering, or if the capsules do not look quite right.

Check with your doctor if you:

- have any other medical conditions, especially the following:
  - epilepsy - metoclopramide may increase the risk of you having a fit
  - breast cancer
  - liver or kidney disease
  - Parkinson's disease, a condition affecting muscle control and movement
  - you have had movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs after taking metoclopramide or medicines used to calm emotional and mental problems.

Tell your doctor or pharmacist if you plan to have surgery.

METOMAX should not be taken immediately after certain types of operations.

Tell your doctor or pharmacist if you have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.

Talk to your doctor or pharmacist if you are not sure whether you should start taking METOMAX.

During treatment with METOMAX, tell your doctor straight away if you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is taken at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

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

Do not take METOMAX if you are pregnant or intend to become pregnant.

It may affect the developing baby if you take it during pregnancy.**Do not take METOMAX if you are breastfeeding or intend to breastfeed.**

METOMAX passes into breast milk and, although the effect on your baby is not known, there is a possibility that your breastfed baby may be affected.

Use in Children

Do not give METOMAX to children and adolescents under 18 years of age.

The safety of this medicine in children under 18 years of age has not been established.

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 METOMAX may interfere with each other. These include:

- medicines used to prevent blood clots
- medicines used to treat epilepsy
- pain relievers such as codeine and morphine
- some medicines found in travel sickness, hay fever and allergy, stomach cramps, and cough and cold preparations
- medicines used to treat anxiety or help you to sleep
- medicines used to treat certain mental and emotional conditions, such as schizophrenia
- tetracycline antibiotics

- levodopa, a medicine used in the treatment of Parkinson's disease
- digoxin, a medicine used to treat heart failure
- flucloxacillin, an antibiotic, due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment. See Section 2. What should I know before I take METOMAX? for further information.
- other paracetamol-containing products.

These medicines may be affected by METOMAX or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has a more complete list of medicines to avoid while taking METOMAX.

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

4. How do I take METOMAX?

How much to take

- The initial dose for adults is 1 to 2 capsules and then 1-2 capsules every 4 hours, as needed.
- Do not take more than 6 capsules in 24 hours.

Do not take more than the recommended dose.

How to take METOMAX

Swallow the capsules whole with a full glass of water.

When to take METOMAX

METOMAX should be taken at the first sign of a migraine attack.

How long to take it for

METOMAX is not intended for long-term use.

Do not take it for longer than 48 hours at a time unless advised to by a doctor.

If you forget to take METOMAX

If symptoms persist, 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 when to take your medicine, ask your pharmacist for some hints.

If you take too much METOMAX

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

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.

There is a risk of delayed, serious liver damage.

5. What should I know while taking METOMAX?

Things you should do

- Tell your doctor or pharmacist if nausea, vomiting or headache persists or worsens.
- Tell all doctors, dentists and pharmacists who are treating you that you are taking METOMAX.
- If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking METOMAX.

Tell your doctor straight away if:

- you become pregnant while you are taking METOMAX

Things you should not do

- **Do not take METOMAX for longer than 48 hours at a time unless advised to by a doctor.**
- Do not give this medicine to anyone else, even if they have similar symptoms.
- Do not take METOMAX to treat any other complaints unless your doctor or pharmacist tells you to.
- **Do not take METOMAX with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.**

  No more than 4 g of paracetamol should be taken in any 24 hour period.

Driving or using machines

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

METOMAX may cause drowsiness, tiredness or dizziness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Avoid drinking alcohol while taking METOMAX.

Combining METOMAX with alcohol can make you more sleepy or drowsy.

Looking after your medicine

- Store below 25°C.
- Keep your capsules in the original container until it is time to take them.

Store METOMAX 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.

Getting rid of any unwanted medicine

Do not take this medicine after the expiry date.

If you no longer need to take this medicine or if the expiry date has passed, you can take it to any pharmacy for safe disposal.

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
• drowsiness, tiredness, dizziness restlessness, fatigue • bowel upsets • trouble sleeping • upset stomach • dizziness, headache. • jaundice (yellowing of the eyes or skin)	**Speak to your doctor if you have any of these less serious side effects.**

Serious side effects

Serious side effects	What to do
• anxiety, depression, or agitation • repeated movements of the arms, legs, eyes, mouth, tongue, face and jaw. This may be a sign of tardive dyskinesia, a movement disorder which can be potentially irreversible. • a serious condition that can make blood more	**Call your doctor straight away if you notice any of these serious side effects.** This includes serious side effects which may require medical attention or hospitalisation

Serious side effects	What to do
acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)	
• symptoms of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath • a sudden increase in body temperature, extremely high blood pressure, stiff muscles and severe convulsions. These could be signs of a serious side effect called neuroleptic malignant syndrome • spasms of facial muscles, lockjaw, slurred speech, involuntary eye movements, unnatural positioning of the head and shoulders, severe	**Call your doctor straight away or go to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.** These side effects are rare, but serious and require urgent medical attention or hospitalisation.

Serious side effects	What to do
arching from the neck and back, and general muscle stiffness. • Parkinson's-like symptoms, including muscle tremors, rigidity, and slowness or inability of movement. • wheezing and difficulty breathing • severe drowsiness or sleepiness • bluish colouration to the skin, a symptom of blood condition called methaemoglobinaemia	

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 from your pharmacist without a doctor's prescription.

What METOMAX contains

Active ingredient **(main ingredient)**	paracetamol 500 mg metoclopramide hydrochloride (as monohydrate) 5 mg
Other ingredients **(inactive ingredients)**	• colloidal anhydrous silica • magnesium stearate • purified talc • sodium starch glycollate • black ink (ID 2328, ID 2343) • gelatin capsule size 0 (ID 11306).
Potential allergens	sulfites

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

What METOMAX looks like

METOMAX is a capsule marked with a Greek alpha symbol on the green section and "P500|M5" on the yellow section (AUST R 121343).

Each pack contains 10 capsules.

Who distributes METOMAX

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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METOMAX® is a Viatris company trade mark

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