

METOMAX[®]

paracetamol & metoclopramide hydrochloride (as monohydrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about METOMAX.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor or pharmacist has weighed the risks of you taking METOMAX against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What METOMAX is used for

METOMAX is used to treat nausea experienced with migraine headaches.

Migraine is a condition that is thought to be caused by the widening of certain blood vessels in the brain causing a recurrent headache that normally affects one side of the head.

Migraines are usually described as intense, throbbing or pounding pain that involves the temple, but can sometimes be located in the forehead, around the eye or the back of the head.

There are many symptoms that may accompany migraines; nausea (feeling sick) is one of the most common.

METOMAX contains paracetamol and metoclopramide hydrochloride (as monohydrate).

Paracetamol is an analgesic, used for temporary relief from pain (such as headache). Metoclopramide is an anti-emetic, used to control nausea and vomiting caused by migraine.

Ask your doctor or pharmacist if you have any questions about why METOMAX has been recommended for you.

Your doctor or pharmacist may have recommended METOMAX for another reason.

This medicine is not addictive.

METOMAX is a "Pharmacist Only Medicine". It is available without a doctor's prescription but your pharmacist's advice is required.

Before you take METOMAX

When you must not take it

Do not take METOMAX if you are allergic to:

- paracetamol (e.g. Panadol)
- metoclopramide (e.g. Maxolon, Pramin)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an 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 take METOMAX if you have:

- bleeding from the stomach and/or digestive tract
- intestinal blockage
- recent surgery on the stomach and/or intestine
- phaeochromocytoma, a rare tumour of the adrenal gland. The adrenal gland is located near the kidney.

Do not use if you have epilepsy (fits).

Do not give METOMAX to children under 18 years.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor or pharmacist if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant.

Your doctor or pharmacist will discuss the risks and benefits of taking METOMAX during pregnancy.

Tell your doctor or pharmacist if you are breastfeeding or wish 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.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- epilepsy
- breast cancer
- Parkinson's disease, a condition affecting muscle control and movement
- kidney or liver problems
- 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.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a 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, hayfever 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
- 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 more information on medicines to be careful with or avoid while taking this medicine.

How to take METOMAX

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

Take METOMAX strictly as directed by your doctor or pharmacist.

The initial dose for adults is 1-2 capsules. METOMAX should be taken at the first sign of a migraine attack. If symptoms persist, repeat every four hours.

The maximum dose for adults is 6 capsules in 24 hours.

Do not take more than the recommended dose.

Your dose may be different from those on the pack, depending on your condition and whether or not you are taking any other medicines. Your doctor or pharmacist will advise you.

METOMAX is not recommended for children below 18 years of age.

How to take it

Swallow the capsules whole with a full glass of water.

When to take it

Take METOMAX 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 for more than a few days at time unless advised to buy a doctor.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much METOMAX. Do this even if there are no signs of discomfort or poisoning.

There is a risk of delayed, serious liver damage. You may need urgent medical attention.

If you take too much METOMAX, you may feel dizzy, sleepy or drowsy, confused, sweaty, vomit, have pains in the stomach, have convulsions or fits, or experience uncontrolled muscle movements or notice yellowing of the skin.

While you are taking METOMAX

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking METOMAX.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If your symptoms do not improve, or if they become worse, tell your doctor.

Things you must not do

Do not use METOMAX to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they have similar symptoms.

Do not take METOMAX with any other products containing paracetamol, unless advised to do so by a doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery 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.

Avoid drinking alcohol while taking METOMAX.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking METOMAX.

METOMAX helps most people to relieve some of the symptoms associated with their migraines. But it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- indigestion
- drowsiness
- fatigue, tiredness
- restlessness
- trouble sleeping
- dizziness, headache
- feeling sick, also called nausea
- bowel irregularities.

The above list includes the milder side effects of METOMAX.

Tell your doctor as soon as possible if you notice any of the following:

- unusual changes mood, such as anxiety, depression or agitation
- uncontrolled and 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.

The above list includes serious side effects which may require medical attention or hospitalisation.

If any of the following happen, stop taking METOMAX and see your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- 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

- severe drowsiness or sleepiness
- bluish colouration to the skin, a symptom of blood condition called methaemoglobinaemia.

The side effects listed above are rare, but serious and require urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking METOMAX

Storage

Keep METOMAX where children cannot reach it.

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

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

If you take the capsules out of the pack they will not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store METOMAX or any other medicine in the bathroom or near a sink.

Do not leave METOMAX in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor or pharmacist tells you to stop taking METOMAX, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

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

Each pack contains 10 capsules.

Ingredients

The active ingredient in METOMAX capsules is paracetamol 500 mg and metoclopramide hydrochloride 5 mg (as metoclopramide hydrochloride monohydrate).

The capsules also contain the following inactive ingredients:

- colloidal anhydrous silica
- magnesium stearate
- purified talc
- sodium starch glycollate
- black ink (PI 2328, 2343)
- gelatin capsule size 0 (PI 11306).

METOMAX contains sulfites.

Supplier

METOMAX is supplied in Australia by:

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

Australian registration number:

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METOMAX® is a Viatris company trade mark

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