MAXOLON®
Metoclopramide hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Maxolon.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Maxolon against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Maxolon is used for

In adults over 20 years this medicine is used to:

- treat nausea and vomiting caused by infectious diseases, migraine, kidney disease, child birth, 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.

In young adults and children under 20 this medicine is used to:

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

This medicine 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.

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

Your doctor may have prescribed it for another reason.

Before you or your child take Maxolon

When you or your child must not take it

Do not take Maxolon if you or your child have

- any medicine containing Metoclopramide
- 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 Maxolon if you or your child have any of the following:

- active bleeding from the stomach and/or digestive tract.
- blockage of the stomach and/or digestive tract.

Do not take Maxolon if you or your child have any of the following:

- recent surgery of the stomach and/or digestive tract.
- Phaeochromocytoma (an adrenaline-producing tumour of the adrenal gland).

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 or your child should start taking this medicine, talk to your doctor.

Before you or your child start to take it

Tell your doctor if you or your child have

- allergies to any other medicines, foods, preservatives or dyes.

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

- epilepsy
- Parkinson’s disease
- liver or kidney problems.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your or your child’s doctor about any of the above, tell him/her before you or your child start taking Maxolon.

Taking other medicines

Tell your doctor or pharmacist if you or your child are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

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

- tranquilizers 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.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Maxolon

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 box, ask your doctor or pharmacist for help.

How much to take

Follow your doctor’s instructions about how much Maxolon to use.

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

The total daily dosage of Maxolon, especially for children and young adults, should not normally exceed 0.5mg/kg bodyweight. Space the doses as evenly as possible throughout the day.

Tablets (10 mg)

- 20 + years - 1 tablet every 8 hours
- 15 to 20 years - ½ to 1 tablet every 8 hrs
- 5 to 14 years - Use Ampoules Only
- 3 to 5 years - Use Ampoules Only
- 1 to 3 years - Use Ampoules Only
- Under 1 year - Use Ampoules Only

Ampoules (10 mg/2 mL)

Your doctor will decide the dose of Maxolon ampoules to be given and how long it is to be administered.

The usual dose of Maxolon is:

- 20 + years - 10 mg every 8 hours
- 15 to 20 years - 5 to 10 mg every 8 hours
- 5 to 14 years - 2.5 to 5 mg every 8 hours
- 3 to 5 years - 2 mg every 8 to 12 hours
- 1 to 3 years - 1 mg every 8 to 12 hours
- Under 1 year - 1 mg every 12 hours

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

How to take it

Tablets:

Swallow the tablets with a full glass of water.

The tablets can be broken in half (along the break-line).

Ampoules:

Your doctor or Nurse will inject the necessary dose of Maxolon.

It may be given by injection in the muscle of the upper arm, buttock or into a vein. The doctor will decide the best method of injection.

Do not exceed the prescribed dose

When to take it

Take the medicine at about the same time each day.

Taking it at the 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

How long to take it

Continue taking the medicine for as long as your doctor tells you.

If you or your child forget to take it

Take it as soon as you remember, and then go back to taking the medicine as you would normally.

Do not take a double dose to make up for the dose that was 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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

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If you take too much (overdose)
Immediately telephone your doctor or the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much Maxolon. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.
Symptoms of an overdose may include drowsiness, confusion, tremor, twitching or uncontrolled spasm of muscles.

While you or your child are using Maxolon

Things you must do
If you or your child's vomiting or nausea persist, tell your doctor.
If you or your child are about to be started on any new medicine, remind your doctor and pharmacist that you or your child are taking Maxolon.
Tell any other doctors, dentists, and pharmacists who treat you or your child that you or your child are taking this medicine.
If you or your child are going to have surgery, tell the surgeon or anaesthetist that you or your child are taking this medicine.
It may affect other medicines used during surgery.
If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do
Do not use Maxolon to treat any other complaints unless your doctor tells you to.
Do not give your or your child's medicine to anyone else, even if they have the same condition.

Things to be careful of
Be careful driving or operating machinery until you know how Maxolon affects you. This medicine 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 if riding bicycles or climbing trees.

Be careful when drinking alcohol while you are taking this medicine.
If you drink alcohol, it may make you sleepy.

Side effects
Tell your doctor or pharmacist as soon as possible if you or your child do not feel well while taking Maxolon.
This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.
You or your child 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:

- dizziness, headache
- bowel irregularities
- insomnia

The above list includes the more common side effects of your medicine. They are usually mild and short-lived

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

- 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

The above list includes serious side effects that may require medical attention. Serious side effects are rare.
If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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 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.
- tardive dyskinesia, uncontrollable twitching or jerking movements of the arms and legs

The above list includes very serious side effects. You or your child may need urgent medical attention or hospitalisation. These side effects are very rare.
Tell your doctor or pharmacist if you notice anything that is making you or your child feel unwell.
Other side effects not listed above may also occur in some people.

After taking Maxolon

Storage
Keep your medicine in the pack until it is time to take it.
If you take the tablets out of the pack they may not keep well.
Keep your tablets in a cool dry place where the temperature stays below 30°C.

Maxolon ampoules will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place where the temperature stays below 25°C.

Do not store Maxolon or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.
Heat and dampness can destroy some medicines.
Keep it 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.

Disposal
If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Maxolon ampoules are usually given in a hospital setting. Your pharmacist will dispose of any left over Maxolon in this case.

Product description

What it looks like
Maxolon tablets: round white tablets marked with Maxolon on one side and has a break line on the other side.

Ingredients
Maxolon tablets contain 10 mg of metoclopramide as the active ingredient.
It also contains:

- starch - maize
- silica - colloidal anhydrous
- magnesium stearate
- starch - pregelatinised maize
- lactose

Maxolon injections supplied in ampoules contain 10mg/2mL of metoclopramide as the active ingredient.
It also contains:

- Sodium chloride
- Water for injections - purified

Maxolon preparations do not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier
Maxolon is supplied in Australia by:

Valeant Pharmaceuticals Australasia Pty Ltd
Level 7, Suite 7/02, 3 Rider Boulevard, Rhodes NSW 2138
® = Registered Trademark

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Maxolon 10mg/2mL injection AUST R 40204