

APO-METOCLOPRAMIDE

Contains the active ingredient metoclopramide (as metoclopramide hydrochloride monohydrate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about metoclopramide. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Metoclopramide. It contains the active ingredient metoclopramide hydrochloride monohydrate.

In adults over 20 years old this medicine is used:

- to treat nausea and vomiting caused by infectious diseases, kidney disease, child birth, other medications, cancer, or following surgery, chemotherapy or radiation treatment

- to 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
- to help with passing tubes into the intestine.

In young adults between 15 to 20 years old this medicine is used as a second therapy option to:

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

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.

Use in children

These tablets should not be used for children under 15 years of age.

Before you take this medicine

When you or your child must not take it

Do not take this medicine if:

- **You or your child have the following:**
 - **active bleeding from the stomach and/or digestive tract**
 - **blockage of the stomach and/or digestive tract**
 - **recent surgery of the stomach and/or digestive tract**
 - **phaeochromocytoma (an adrenaline - producing tumour of the adrenal gland)**
 - **have epilepsy (fits or seizures)**
 - **porphyria (a rare blood pigment disorder).**
- **You or your child take other medication such as antipsychotic/neuroleptic medication and certain antidepressants that can cause movement disorders (extrapyramidal reactions).**
- **Your child is younger than 15 years of age. You or your child are hypersensitive to, or have had an allergic reaction to, metoclopramide or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing;

swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you or your child are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - Parkinson's disease
 - liver or kidney problems
 - high blood pressure
 - depression.

3. You are currently pregnant or you plan to become pregnant.
4. You are currently breastfeeding or you plan to breastfeed.
5. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with metoclopramide. These include:

- tranquilizers or anti-anxiety medications
- strong pain relievers (e.g. codeine or morphine)
- phenothiazines, used to treat mental and emotional disorders
- sedatives or sleeping medication
- atropine-like medications (e.g. some cold preparations, relief of stomach cramps or spasms, travel sickness)
- tetracycline antibiotics, paracetamol, levodopa
- digoxin
- cyclosporin used to help prevent organ transplant rejection or to treat certain problems with the immune system.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with this medicine.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your age and your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The total daily dosage of metoclopramide, especially for young adults, should not normally exceed 0.5 mg/kg bodyweight (maximum 30 mg daily). Space the doses as evenly as possible throughout the day.

20 + years

One 10 mg tablet every 8 hours.

15 to 20 years (second line)

One 5 mg to 10 mg tablet every 8 hours.

Young adults are very sensitive to the effects of this medicine. Your doctor will normally start treatment at the lower dose.

Tablets should not be used in children less than 15 years of age.

How to take it

Swallow the tablets with a full glass of water. The 10 mg tablets can be broken in half (along the breakline).

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

Take the medicine 30 minutes before meals.

How long to take it for

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

Maximum treatment duration is 5 days.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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 are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- your vomiting or nausea persists
- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

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 when 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- drowsiness, tiredness
- restlessness
- dizziness or headache
- bowel irregularities
- insomnia.

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

These may be serious side effects and you may need medical attention:

- 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
- increasing number of infections
- elevated temperature with no clear cause
- breast enlargement or milk secretions.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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
- yellowing of the skin (jaundice).

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to this medicine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Metoclopramide Dosage Form looks like

5 mg tablets:

APO-Metoclopramide 5 mg tablets are white to off-white, circular, biconvex film-coated tablets plain on both sides

10 mg tablets:

APO-Metoclopramide 10 mg tablets are white to off-white, circular, biconvex film-coated tablets with breakline on both sides

Available in blister packs of 25's and 100's

Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 5 mg or 10 mg of metoclopramide hydrochloride monohydrate as the active ingredient.

It also contains the following inactive ingredients:

- maize starch
- pregelatinised maize starch
- microcrystalline cellulose
- colloidal anhydrous silica
- stearic acid
- hypromellose
- macrogol 6000
- titanium dioxide
- purified talc.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Metoclopramide 10 mg tablets (blister pack) AUSTR:
196502

Sponsor

Apotex Pty Ltd

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This leaflet was last updated in March 2018.