

METOCLOPRAMIDE AN

Metoclopramide hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Metoclopramide AN. 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 Metoclopramide AN 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 Metoclopramide AN is used for

In adults over 20 years 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.
- 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 between 15 to 20 years this medicines is used to:

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

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

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 Metoclopramide AN

When you or your child must not take it

Do not take Metoclopramide AN if you or your child have an allergy to:

- 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 Metoclopramide AN 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.
- recent surgery of the stomach and/or digestive tract.
- Phaeochromocytoma (an adrenaline- producing tumour of the adrenal gland).
- have epilepsy (fits or seizures).
- take other medication such as antipsychotic/neuroleptic medication and certain antidepressants that can cause movement disorders (extrapyramidal reactions).

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:

- Parkinson's disease
- liver or kidney problems
- high blood pressure
- asthma

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 Metoclopramide AN.

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 Metoclopramide AN 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 Metoclopramide AN 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 Metoclopramide AN

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 Metoclopramide AN to use.

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

The total daily dosage of Metoclopramide AN, especially for children and young adults, should not normally exceed 0.5 mg/kg bodyweight.

Space the doses as evenly as possible throughout the day.

Tablets

20 + years - One 10 mg tablet every 8 hrs

15 to 20 years - One 5 mg to 10 mg tablet every 8 hrs

Tablets should not be used in children less than 15 years of age. Young adults are very sensitive to the effects of Metoclopramide AN. Your doctor will normally start treatment at the lower dose.

How to take it

Tablets: Swallow the tablets with a full glass of water.

The tablets can be broken in half (along the breakline).

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.

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 PCA-Metoclopramide. 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 Metoclopramide AN

Things you must do

If your or your child's vomiting or nausea persists, 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 PCA-Metoclopramide.

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 Metoclopramide AN 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 Metoclopramide AN 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 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well while taking Metoclopramide AN.

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:

- drowsiness, tiredness
- restlessness
- 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 Metoclopramide AN

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 25°C.

Do not store Metoclopramide AN 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.

Product description

What it looks like

- Metoclopramide AN 10 mg tablets are white to off-white, circular, biconvex film-coated tablets with breakline on both sides.
- Metoclopramide AN 5 mg tablets are white to off-white, circular, biconvex film-coated tablets plain on both sides.

Ingredients

Metoclopramide AN 10 mg tablets contain 10 mg of metoclopramide and the 5 mg tablets contain 5 mg of metoclopramide as the active ingredient.

It also contains:

- Maize Starch
- Pregelatinised maize Starch
- Microcrystalline Cellulose
- Colloidal anhydrous Silica
- Steric acid
- Hypromellose
- Macrogol 6000
- Titanium dioxide
- Purified Talc

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

Sponsor

Amneal Pharma Australia Pty Ltd
12 River St
South Yarra, VIC 3141

Australian Registration Numbers

- METOCLOPRAMIDE AN 5 mg
-
AUST R 196500
- METOCLOPRAMIDE AN 10 mg -
AUST R 196492

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