

# APO-METOCLOPRAMIDE

Contains the active ingredient metoclopramide (metoclopramide hydrochloride (as monohydrate))

## Consumer Medicine Information

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

### What is in this leaflet

This leaflet answers some common questions about this medicine. 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 this medicine 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 this medicine is used for

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

In adults over 20 years old metoclopramide 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 when other therapies haven't worked 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.**

**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.

### Before you take this medicine

#### When you must not take it

**Do not take this medicine if you 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 give this medicine to a child under the age of 15 years.**

Safety and effectiveness in children younger than 15 years have not been established.

**Do not take this medicine if you have any of the following medical conditions:**

- 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
- pheochromocytoma (an adrenaline - producing tumour of the adrenal gland)
- epilepsy (fits or seizures)
- porphyria (a rare blood pigment disorder)

**Do not take this medicine if you 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 should start taking this medicine, talk to your doctor.**

#### Before you start to take it

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

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

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

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

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

#### Taking other medicines

**Tell your doctor or pharmacist if you 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 may interfere with each other. 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

These medicines may be affected by metoclopramide 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 and pharmacist have more information on medicines to be careful with or avoid while taking 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.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

#### 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.

**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

10 mg every 8 hours.

#### 15 to 20 years (second line)

5 mg to 10 mg 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.**

**Elderly patients are very sensitive to the effects of this medicine.**

Do not exceed the prescribed dose, and where prolonged therapy is necessary, patients should be regularly reviewed.

#### How to take it

**Swallow the tablets with a full glass of water.**

The 10 mg tablets can be broken in half (along the break line).

#### When to take it

**Take your 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 for

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

Maximum treatment duration is 5 days.

#### If you forget to take it

**If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.**

**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 the dose that 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 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 (telephone 13 11 26) 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 of this medicine. 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, feelings of anxiety or restlessness, headache, vertigo, nausea, vomiting, constipation, weakness, low blood pressure and dry mouth.

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### While you are taking this medicine

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#### *Things you must do*

**If your vomiting or nausea persists, tell your doctor.**

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

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

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.** It may interfere with the results of some tests.

**Keep all your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

#### *Things you must not do*

**Do not take this medicine to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without 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.

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### Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

**Do not be alarmed by the following lists 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 if you notice any of the following:**

- drowsiness, tiredness
- restlessness
- dizziness or headache
- bowel irregularities
- insomnia
- anxiety
- agitation

**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
- increasing number of infections
- elevated temperature with no clear cause
- breast enlargement or milk secretions
- depression
- urinary incontinence and frequency

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

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- 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)
- symptoms of an allergic reaction including 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

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

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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

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### Storage and disposal

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#### *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 see or 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.

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### Product description

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#### *What APO-Metoclopramide Tablets look like*

##### **10 mg tablets:**

APO-Metoclopramide 10 mg tablets are white to off-white, circular, biconvex film-coated tablets with break line on both sides. AUST R 196502.

Available in blister packs of 25 and 100.

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

#### *Ingredients*

Each tablet contains 10 mg of metoclopramide hydrochloride (as 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, lactosefree, sucrose-free, tartrazine-free and free of other azo dyes.

#### *Sponsor*

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