

AXCEL METOCLOPRAMIDE TABLET

Metoclopramide Hydrochloride (10mg)

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What Axcel Metoclopramide Tablet is used for

Axcel Metoclopramide Tablet are used for:

Adult population:

- Symptomatic treatment of nausea and vomiting, including acute migraine induced nausea and vomiting.
- Prevention of delayed chemotherapy induced nausea and vomiting (CINV).
- Prevention of radiotherapy induced nausea and vomiting (RINV).

Age 9-18 years population:

- Prevention of delayed chemotherapy induced nausea and vomiting (CINV) as a second line option.

How Axcel Metoclopramide Tablet works

Metoclopramide HCl promotes involuntary constriction and dilation of the muscle in the oesophagus (food pipe) and stomach, increases the tone of the muscular ring in between the stomach and oesophagus to prevent the backflow of stomach content and tends to speed gastric emptying.

Before you use Axcel Metoclopramide Tablet

-When you must not use it

Do not take Axcel Metoclopramide Tablet if:

- You are hypersensitive to Metoclopramide or to any of the ingredients listed.
- You have stomach and intestine bleeding, obstruction or tear.
- You are confirmed or suspected pheochromocytoma (tumor of the adrenal glands), due to the risk of severe high blood pressure.
- You have history of tranquilizer use or metoclopramide-induced tardive dyskinesia (involuntary, repetitive body movements).
- You have seizures or parkinson (movement disorder).
- It is combination with medicine such as levodopa or dopaminergic agonists.
- You have known history of methaemoglobinaemia (abnormal blood pigment levels) with metoclopramide or of NADH cytochrome-b5 deficiency.
- Central nervous system depressants (used to treat anxiety, acute stress reactions, and panic attacks).
- Digoxin (used to treat various heart conditions).
- Cyclosporine (used to prevent organ rejection after transplant).
- Paracetamol, Aspirin (used to treat pain and fever).
- Gonadoreline (used for hormonal disorder).
- Monoamine oxidase inhibitors (MAOIs) (used to treat depression).

-Before you start to use it

Tell your doctor if:

- You are pregnant. Metoclopramide can be used during pregnancy if really needed but it should be avoided at the end of pregnancy.
- You are breastfeeding. Metoclopramide is not recommended during breastfeeding because it is found in breast milk at low level.
- You have underlying neurological (brain) disorder.
- You are receiving medicines that affect your heart rate or blood pressure.
- You have kidney or liver failure

-Taking other medicines

You should tell your doctor or pharmacist if you are taking the following medicine as it may interact with your Axcel Metoclopramide Tablet:

- Phenothiazines (used to treat mental and emotional disorders).
- Pergolides, Levodopa, Bromocriptine (used to treat Parkinson's Disease).

How to use Axcel Metoclopramide Tablet

-How much to use

To be used orally.

Adults:

The recommended single dose is 10mg, repeated up to three times daily.

The maximum recommended daily dose is 30mg or 0.5mg/kg body weight.

The maximum recommended treatment duration is 5 days.

Prevention of delayed chemotherapy induced nausea and vomiting (CINV) (Population aged 9-18 years):

The recommended dose is 0.1 to 0.15 mg/kg body weight, repeated up to three times daily by oral route.

The maximum dose in 24 hours is 0.5mg/kg body weight.

Dosing table:

Age	Body weight	Dose	Frequency
9-18 years	30-60 kg	5mg	Up to 3 times daily
15-18 years	Over 60kg	10mg	Up to 3 times daily

The maximum treatment duration is 5 days for prevention of delayed chemotherapy induced nausea and vomiting (CINV).

Tablets are not suitable for use in children weighing less than 30kg. Other pharmaceutical forms/strengths may be more appropriate for this population.

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Frequency: A minimal interval of 6 hours between two intakes is to be respected, even if vomiting or rejection of the dose occurs.

Elderly:

In elderly a dose reduction should be considered, based on kidney and liver function and overall frailty.

Kidney impairment:

In individuals with end stage kidney disease, the daily dose should be reduced by 75%.

In individuals with moderate to severe kidney impairment, the dose should be reduced by 50%.

Liver impairment:

In individuals with severe liver impairment, the dose should be reduced by 50%.

-When to use it

Your doctor will decide when it is appropriate for you to use Axcel Metoclopramide Tablets according to the type of condition you have.

-How long to use it

Treatment should not exceed 3 months. Continue taking Axcel Metoclopramide Tablet for as long as doctor recommends.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Symptoms of overdosage includes:

- Constipation
- Diarrhoea
- Drowsiness
- Weakness
- Uncontrolled body movements.

It is advisable for you to contact and inform your doctor if you did take

Axcel Metoclopramide Tablet too much.

While you are using it

-Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Axcel Metoclopramide Tablet.
- Tell your doctor immediately if you become pregnant while talking this medication.

-Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Axcel Metoclopramide Tablet to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

- Avoid doses exceeding 0.5mg/kg/day.
- Avoid prolonged treatment with high dosage.

Side effects

Like all medicines, Axcel Metoclopramide Tablet can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following side effects have been reported:

Rare side effects:

- Drowsiness.
- Repetitive muscle contractions. These are reversible usually disappearing within 24 hours of stopping treatment.
- Involuntary body movements.
- Raised levels of a hormone called prolactin in the blood which may cause milk production.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and disposal of Axcel Metoclopramide Tablet

-Storage

Keep Axcel Metoclopramide Tablet out of reach of children.

Store below 30°C. Keep container well closed and protect from light.

-Disposal

Do not use Axcel Metoclopramide Tablet after the expiry date which is stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

-What it looks like

Axcel Metoclopramide Tablet is a light yellow, biconvex, round tablet, 7.1mm in diameter with a single score-line on one side and marked KOTRA logo on the other side.

-Ingredients

-Active Ingredient:

Metoclopramide Hydrochloride

-Inactive Ingredients:

Pregelatinized Starch, Quinoline Yellow, Corn Starch, Lactose, Aerosil, Magnesium Stearate and Purified Water.

-MAL Number

MAL19921470AZ

Manufacturer and product registration holder

Kotra Pharma (M) Sdn Bhd
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

Date of revision

29/01/2018

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Serial number

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