MEXOMIDE TABLET

Metoclopramide Hydrochloride (10mg)

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What Mexomide Tablet is used for Adult population

Mexomide Tablet is indicated in adults for:

- Prevention of nausea and vomiting induced by chemotherapy and radiotherapy
- Symptomatic treatment of nausea and vomiting.

Children population

Mexomide Tablet is indicated in children (aged 9-18 years) for:

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

How Mexomide Tablet works:

Metoclopramide increases gastric motility and accelerates gastric emptying. It also has an anti-vomiting action that is due partly to its local action on the stomach and intestinal tract and partly to a direct action on the central nervous system which controls the body and mind.

Before you use Mexomide Tablet

- When you must not use it

Do not take this medicine if you have any of the following;

- Hypersensitivity to the metoclopramide or to any of the ingredients listed.
- 2) Gastrointestinal bleeding, obstruction or perforation.
- Confirmed or suspected phaeochromocytoma (noncancerous (benign) tumor that develops in an adrenal gland)
- History of uncontrolled body movement induced by metoclopramide or medicines that reduce nerve function.
- 5) Epilepsy
- 6) Parkinson's disease.
- 7) Taking medicine such as levodopa or dopaminergic agonists.

- 8) Known history of methemoglobinemia (blood disorder in which too little oxygen is delivered to your cells).
- 9) Use in children less than 1 year of age.

Pregnancy and lactation

Do not take Mexomide Tablet if you are pregnant, trying to get pregnant or think you may be pregnant especially during the first trimester of pregnancy.

Do not take Mexomide Tablet if you are breast-feeding. Metoclopramide is excreted in breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell your doctor or pharmacist if you experience:

- Moderate to severe kidney impairment
- Severe liver impairment
- Nerve problems
- Heart problems

- Taking other medicines

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

Metoclopramide should not be taken with

- Neuroleptics tranquilizer
- Anticholinergic agents
- Medicines that used for Parkinson disease (e.g. levodopa)
- Central Nervous System (CNS) depressants
- Digoxin treat heart conditions
- Cimetidine treat heart burn and stomach ulcers
- Paracetamol relieve pain and fever
- Tetracycline antibiotic

How to use Mexomide Tablet

- <u>How much to use</u> Adults:

The recommended single dose is 10 mg, repeated up to three times daily. The maximum recommended daily dose is 30 mg or 0.5 mg/kg body weight.

Prevention of delayed chemotherapy induced nausea and vomiting (Children 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 recommended dose in 24 hours is 0.5 mg/kg body weight.

Dosing table

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

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

A minimum interval of 6 hours between two administrations is to be respected, even if or vomiting of the dose occurs.

- How long to use it

Continue taking Mexomide Tablet for as long as your doctor recommends.

The maximum recommended treatment duration is 5 days.

- 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)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think 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.

Taking too many tablets may cause extrapyramidal reactions such as slurred speech, tremor, anxiety, distress and slowed thinking.

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While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking Mexomide Tablet.

Tell your doctor immediately if you become pregnant while taking 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 Mexomide Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines
This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Mexomide Tablet can cause side effects, although not everybody gets them.

Metoclopramide may cause extrapyramidal reactions, especially in young people. Other adverse effects include bowel upsets, drowsiness and fatigue, dizziness, restlessness and anxiety. Excessive or inappropriate production of milk and enlargement of a man's breasts have been reported.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

Storage and Disposal of Mexomide Tablet

- Storage

Keep container tightly closed. Store in dry place below 25°C. Protect from light. Keep out of reach of children.

- <u>Disposal</u>

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

White in colour, flat, round and scored; uncoated tablet.

- Ingredients
- Active ingredient
 Metoclopramide Hydrochloride
- Inactive ingredients Gelatin, Lactose, Magnesium Stearate, Starch, Dried Starch.
- <u>MAL number:</u> MAL19910164AZ

Manufacturer & Product Registration Holder

Dynapharm (M) Sdn. Bhd. 2497, Mk 1, Lorong Perusahaan Baru 5, Kawasan Perusahaan Perai 3, 13600 Perai, Pulau Pinang, Malaysia.

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