

MOTIDONE TABLET

Domperidone (10mg)

What is in the leaflet

1. What MOTIDONE is used for
2. How MOTIDONE works
3. Before you use MOTIDONE
4. How to use MOTIDONE
5. While you are using it
6. Side effects
7. Storage and Disposal of MOTIDONE
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What MOTIDONE is used for

The indigestion symptom complex that is often associated with delayed gastric emptying, gastro-oesophageal reflux and oesophagus inflammation:

- epigastric sense of fullness, early satiety, feeling of abdominal distension, upper abdominal pain;
- bloating, burping, flatulence
- nausea and vomiting;
- heartburn with or without back flow of gastric contents in the mouth.

How MOTIDONE works

MOTIDONE is an antiemetic and a prokinetic medicine. It works by blocking the action of a chemical messenger in the brain which causes the feeling of nausea and vomiting, as well as increasing the movement or contractions of the stomach and intestines, allowing food to move more easily through the stomach.

Before you use MOTIDONE

- When you must not use it

Do not take MOTIDONE if:

- you have an allergy to MOTIDONE or any of the ingredients at the end of this leaflet.
- you have a tumour of the pituitary gland called prolactinoma
- bleeding, obstruction or perforation in the stomach and intestines.
- prevention of post-operative vomiting or for long term usage
- you have cardiac diseases such as heart failure due to increased risk of abnormal heart beat

Do not take MOTIDONE if you are taking any of the following medicines: clarithromycin (antibiotic).

- Before you start to use it

You must tell your doctor if:

- you are pregnant or planning to become pregnant. This medicine should be used during pregnancy only if clearly needed.
- you have or have had liver disease.
- you had breast cancer.
- you have experience any cardiac symptoms.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking MOTIDONE.

- 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 may interfere with MOTIDONE tablet. These include:

- Anticholinergic medicines used to treat stomach cramp
- Antacid, medicines for heartburn
- Antisecretory medicines
- Bromocriptine, Atropine medicines used to treat Parkinson disease

How to use MOTIDONE

- How much to use

You should always take the lowest amount of MOTIDONE that works for you and you should not take it for longer than is necessary. Although the amount of MOTIDONE you should usually take is described below, your doctor may adjust your dose to your personal needs.

MOTIDONE is most effective if taken 15-30 minutes before meals.

Adults and adolescents (12 years of age and over) weighing 35 kg or more; children weighing 35 kg or more:

Tablets: Take 1 tablet 3 to 4 times a day. Do not take more than 4 tablets per day (40 mg/day).

Infants and children less than 12 years of age and weighing less than 35kg:

The effectiveness of MOTIDONE has not been established in infants and children under 12 years of age with a body weight of <35 kg

- When to use it

It is best taken 15 to 30 minutes before meals or food, and if necessary at bedtime.

- How long to use it

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

- If you forget to use it

If it is almost time for 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 capsules 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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much MOTIDONE Tablet.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Some of the symptoms of an overdose may include:

- drowsiness,
- uncontrolled movements

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking MOTIDONE.

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking MOTIDONE.

- Things you must not do

Do not give MOTIDONE to anyone else, even if they have

the same condition as you.

Do not use MOTIDONE to treat any other complaints unless your doctor tells you to.

Do not use MOTIDONE if you are breast feeding or wish to breastfeed unless the expected benefits outweigh any potential risk.

- Things to be careful of

Be careful driving or operating machinery until you know how MOTIDONE affects you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

There have been reports of adverse effects possibly related to increases in serum prolactin. These effects include: enlarged breast in men, breast tenderness, swelling of the breasts, irregular menses, abnormal absence of period, a decrease or loss of sex drive, breast secretion and breastmilk secretion. These effects occurred in people who received up to 120 mg per day in four divided doses.

Tell your doctor if you experience any of the following:

- headache, trouble sleeping, dizziness, tiredness or irritability
- dry mouth or thirst
- stomach cramps, diarrhoea, constipation, nausea, changes in appetite or heartburn
- rash or itchy skin
- itchy eyes and crusty eyelids with discharge
- mouth ulcers or cold sores.
- swollen limbs, rapid/irregular heartbeat

These are mild side effects of MOTIDONE. Tell your doctor if they continue.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of MOTIDONE

- Storage

Keep the medicine in a place where the temperature stays below 30°C. Protect from light.

Do not store MOTIDONE Tablet or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep MOTIDONE Tablet 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 MOTIDONE Tablet or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product Description

- What it looks like

MOTIDONE TABLET 10mg
is an oblong shaped tablet,
pink in colour with marking
“DUO”.

- Ingredients

Active ingredient:

- Domperidone

Inactive ingredients:

- Promigel
- Tween 80
- Polyvinylpyrrolidone
- Lactose
- Aerosil
- Carmoisine
- Cornstarch
- Magnesium stearate

- MAL number

MAL19984023AZ

Product Registration Holder & Manufacturer

Duopharma (M) Sdn. Bhd.
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

Date of Revision

01/02/2021

Serial Number:

NPRA(R2/1)190814/221

