

MOTIDOM TABLET/ORAL SUSPENSION®

Domperidone (10mg, 1mg/ml)

What is in the leaflet

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

What Motidom is used for

Motidom is used for the relief of the symptoms of nausea and vomiting.

How Motidom works

It works by blocking the chemical messenger in the brain that causes the feeling of nausea and vomiting. It also increases the movement or contractions of the stomach and intestine, allowing food to move easily through your digestive system.

Before you use Motidom

- When you must not use it

- Have allergic reaction to the active ingredient domperidone, or to any other ingredients in this product.
- Have a tumour of the pituitary gland in your brain that overproduces the hormone prolactin (prolactinoma)
- Have moderate to severe liver impairment
- Have heart problems
- Have gastrointestinal bleeding, obstruction or perforation
- Are taking certain medicines (Refer to section "Taking other medicines")

Motidom is not recommended for routine prevention of postoperative vomiting or for long term administration of more than 12 weeks.

- Before you start to use it

Tell your doctor if you:

- Have kidney problem
- Have electrolyte abnormalities
- Have allergies to any other medicines, foods, preservatives or dyes.

If you are not sure whether you should start taking this product, consult your doctor.

- Taking other medicines

Some medicine and **Motidom** may interfere with each other. Do not use

Motidom if you are taking certain medicines for:

- Irregular heartbeat (e.g. amiodarone)
- Psychology disorder (e.g. haloperidol) or depression (e.g. citalopram, escitalopram)
- Antibiotics (e.g. erythromycin, levofloxacin, moxifloxacin, clarithromycin), antifungals, antimalarial
- Digestive problems (e.g. cisapride)
- Allergy or flu (e.g. antihistamine)
- Cancer

Tell your doctor if you are taking:

- Medicines for heart problem (diltiazem, verapamil)
- Antibiotics (Azithromycin, roxithromycin)

- Pregnancy and lactation

Tell your doctor if you are pregnant, think you are pregnant or planning to become pregnant. **Motidom** is not recommended during pregnancy.

Tell your doctor if you are breastfeeding or about to start breastfeeding. **Motidom** is not recommended for mothers who are breastfeeding. This is because small amount may pass into the mother's milk.

Motidom should be given only under close medical supervision in infants and only in the opinion of the physician that its expected benefits outweigh the potential risks involved.

How to use Motidom

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

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

Adults and adolescents (12 years of age and over) 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).

Oral suspension: Take 10 mL of oral suspension 3 or 4 times a day. Do not take more than 40mL per day (40 mg/day).

Adults and adolescents weighing less than 35 kg:

Oral suspension: Give 0.25 milliliters of the oral suspension per kilogram of body weight 3 or 4 times a day. The maximum dose per day is 1 mg/kg but do not exceed 35 mg per day.

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

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

- How long to use it

Continue to take your medicines as long as your doctor tells you. Usually, the maximum treatment duration should not exceed one week.

- If you forget to use it

Take your dose as soon as you remember and continue to take it as you would normally. Do not take a double dose to make up for the dose you missed or taking more doses at a time. This may cause unwanted side effects.

- If you use too much (overdose)

If you or anyone else takes too many **Motidom**, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining medicine you have with you.

Drowsiness, agitation, altered consciousness, convulsions, disorientation and uncontrolled movements may be observed after an overdose of **Motidom**.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

While you are using it

- Things you must do

- Always take **Motidom** exactly according to the instructions given to you by your doctor or pharmacist. Check with your doctor or pharmacist if you are unsure.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking **Motidom**.

- Things you must not do

- Do not give this medication to anyone else, even if they have the same condition as you.
- Do not use **Motidom** to treat any other complaints unless your doctor says so.

- Things to be careful of

- Dizziness and sleepiness have been observed following use of domperidone. You are advised not to drive or operate machine or engage in other activities requiring mental alertness and coordination until you know how **Motidom** affects you.
- **Motidom** tablets contain lactose and may be unsuitable for people with problems of lactose intolerance, production or absorption.

Side effects

All medicines can have side effects.

Motidom may cause unwanted side effects although not everybody gets them. Tell your doctor or pharmacist if you notice the following side effects:

• Psychiatric disorders

- Loss of sexual desire, anxiety, depression, agitation, nervousness

• Nervous system disorders

- Sleepiness, headache, difficult to stay still, uncontrolled movement, convulsions, dizziness

• Gastrointestinal disorders

- Dry mouth, diarrhoea

• Skin disorder

- Rash, itching, hives

• Reproductive system and breast disorders

- Abnormal breast milk production, breast pain, breast tenderness, enlarged breast in men, absence or irregular menstruation

• General disorder

- Lack of energy

• Immune system disorder

- Allergic reactions including swelling beneath the skin.

• Eye disorders

- Movements of the eyeballs into a fixed position, usually upwards.

• Heart disorders

- Irregular heartbeat, abnormal heart rhythm, sudden death caused by loss of heart function.

• Kidney and urinary disorders

- Urinary retention

• Lab investigations

- Liver function test abnormal, blood prolactin increased

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 [Consumers →> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Motidom

Storage

Store in a cool dry place below 30°C.

Keep in original package to protect from light, heat and moisture.

Do not store **Motidom** or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of the reach and sight of children.

- Disposal

Do not use **Motidom** after the expiry date which is stated on the carton and blister. If your doctors tell you to stop taking **Motidom** or the expiry date has passed, ask your pharmacist what to do with the remaining medicines.

Product Description

- What it looks like

Motidom Tablet is a white, round biconvex tablet with a bisec-line on one side.

Motidom Oral Suspension 1mg/ml is a white liquid suspension.

Ingredients

- Active ingredient

Motidom tablet: Each tablet contains 10mg of domperidone.

Motidom Oral Suspension 1mg/ml:

Each 5ml suspension contains 5mg of domperidone.

- Inactive ingredients

Motidom Tablet

Glycerine, povidone, sodium starch glycolate, lactose monohydrate, talc, magnesium stearate and purified water.

Motidom Oral Suspension 1mg/ml

Saccharin sodium, sorbitol, myacide SP,

xanthan gum, microcrystalline cellulose, carboxymethyl cellulose sodium, concentrated raspberry juice, propylene glycol, methyl paraben, propyl paraben, polysorbate, alcohol and purified water.

- Packing

Motidom Tablet

Packed in a box of 50 strips x 10 tablets

Motidom Oral Suspension 1mg/ml

Packed in a 30ml bottle.

- MAL Numbers

Motidom Tablet

MAL20021173AZ

Motidom Oral Suspension 1mg/ml

MAL06011683AZ

Manufacturer

Motidom Tablet

T.O Chemicals (1979) Ltd.

280 Soi Sabaijai, Suthisarnwinijai Road, Samsennok, Huay Kwang, Bangkok 10320, Thailand.

Motidom Oral Suspension 1mg/ml

T.O. Pharma Co. Ltd,

101 Soi Ladprao 124, Ladprao Road, Phlapphla, Wangthonglang, Bangkok 10310, Thailand.

Product Registration Holder

IMEKS Pharma Sdn. Bhd.

No. 5 & 9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur, Malaysia.

Date of revision

27/07/2023

Serial number

NPRA(R2/1)230720/1110