

# MOLAX-M<sup>®</sup> FILM COATED TABLET

Domperidone maleate (10mg)

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## What MOLAX-M<sup>®</sup> is used for

MOLAX-M<sup>®</sup> is indicated for the relief of the symptoms of nausea and vomiting.

## How MOLAX-M<sup>®</sup> works

MOLAX-M<sup>®</sup> 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 MOLAX-M<sup>®</sup>

### -When you must not use it

Do not take MOLAX-M<sup>®</sup> if you:

- are allergic to MOLAX-M<sup>®</sup> and other medicines containing domperidone
- have moderate to severe liver impairment
- have electrolyte disturbances

- are allergic to any of the ingredients listed under the Ingredients section of this leaflet
- have a tumour of the pituitary gland known as prolactinoma
- have severe stomach cramps or persistent black stools
- have a pre-existing heart condition.
- have a condition where an increase in stomach or bowel contractions can harm you. For example, if you have had bleeding, a blockage or puncture in your gastrointestinal tract

Do not take MOLAX-M<sup>®</sup> if:

- the packaging is torn or shows signs of tampering.
- the expiry date (Exp.) on the carton has passed.

Please consult your healthcare professional if you are unsure about any of the above.

### -Before you start to use it

Please inform your healthcare professional regarding the following:

- You are pregnant or planning to become pregnant.
- Your baby is under 1 year of age.
- You are breast feeding or wish to breastfeed. (It is not advisable to take MOLAX-M<sup>®</sup> in pregnancy because domperidone is found in the breast milk but at very low levels)
- You have or have ever had liver or kidney disease.

- You are not able to digest lactose which is a sugar found in milk and milk products.

Your doctor will advise you whether MOLAX-M<sup>®</sup> is suitable for you or if you need to adjust the dose.

### -Taking other medicines

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

MOLAX-M<sup>®</sup> may interfere with some medicines. In particular, tell your healthcare professional if you are taking any of the following medicines listed below:

- medicines for treating fungal infections, such as azole antifungals
- antibiotic such as clarithromycin, levofloxacin, and erythromycin
- medicines used to treat high blood pressure or chest pain, such as diltiazem and verapamil.
- Amiodarone, disopyramide, quinidine used to treat irregular heart rate
- Medicines for treating mental disorder such as haloperidol, pimozide
- Antidepressants such as citalopram and escitalopram
- Cisapride used to treat heart burn
- Methadone for treatment of opiate addiction

A more complete list of medicines to be careful with or

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avoid while taking MOLAX-M<sup>®</sup> can be obtained from your healthcare professional.

## How to use MOLAX-M<sup>®</sup>

### -How much to use

The usual dose in adults is one tablet three to four times a day 15-30 minutes before meals.

You should not take more than a total of four tablets in a single day.

MOLAX-M<sup>®</sup> should not be given to children unless indicated for management of nausea and vomiting following cancer chemotherapy or radiation.

Your doctor may reduce the dose if you have kidney disorder.

### -When to use it

Take MOLAX-M<sup>®</sup> as directed by the doctor.

### -How long to use it

MOLAX-M<sup>®</sup> should be continued for as long as your doctor recommends. Usually, the maximum treatment duration should not exceed one week for treatment of acute nausea and vomiting. If nausea and vomiting persists for longer than one week, you should consult your doctor. For other uses, the initial duration of treatment is up to 4 weeks.

### -If you forget to use it

Skip the missed dose if it is almost time for your next dose

and take your next dose when you are supposed to.

Otherwise, take it as soon as you remember, then go back to taking your tablets as you normally do.

Do not double the dose to make up for the missed dose.

Check with your healthcare professional if you are unsure of what to do or if you miss more than one dose.

### -If you use too much (overdose)

Immediately inform your doctor or the National Poison Centre for advice if you suspect that you or anyone else may have taken too much MOLAX-M<sup>®</sup>.

The National Poison Centre can be contacted at:

- 1-800-88-8099 during office hours
- +6012-430 9499 after office hours

Alternatively, go to your nearest hospital. Do this even if you are not experiencing signs of discomfort or poisoning as you may need urgent medical attention.

Taking too much MOLAX-M<sup>®</sup> may result in drowsiness, confusion and uncontrolled movements, such as irregular eye movements, or abnormal posture like twisted neck.

## While you are using MOLAX-M<sup>®</sup>

### -Things you must do

Tell your healthcare professional if you are going to begin any new medicines.

### -Things you must not do

Do not use MOLAX-M<sup>®</sup> to treat any other complaints unless your doctor tells you to.

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

### -Things to be careful of

A risk of unusual heart beat or sudden heart failure has been associated with the use of MOLAX-M<sup>®</sup>. The risk is higher in people older than 60 years or taking more than three tablets daily. MOLAX-M<sup>®</sup> should be used with caution and should be taken at the lowest effective dose. Talk to your doctor if you have a pre-existing heart condition.

## Side effects

All medicines can have side effects which are occasionally serious.

Inform your healthcare professional if you notice any of the following:

- stomach cramps
- rash or itchy skin
- fast or irregular heart beats

This is not a complete list of all possible side effects. Inform

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your healthcare professional if you notice anything making you feel unwell when you are taking, or soon after you have finished taking MOLAX-M<sup>®</sup>.

Please consult your healthcare professional for further information.

You may report any side effects or adverse drug reactions to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

## Storage and Disposal of

### MOLAX-M<sup>®</sup>

#### -Storage

- Keep tablets away from children in a place where they cannot reach.
- Store below 30°C in a tightly close container.


#### -Disposal

Consult your healthcare professional for disposal of leftover tablets that have passed their expiry date or if you have been instructed to stop the medicine.

#### **Product Description**

##### -What it looks like

MOLAX-M<sup>®</sup> tablets are white, round and biconvex film coated tablets with 'M' on one side

and  on the other side. Each box contains 100 tablets.

##### -Ingredients

Active ingredient:

10 milligrams of domperidone maleate in each MOLAX-M<sup>®</sup> tablet.

Inactive ingredients:

Talcum, methylene chloride, sodium starch glycolate, pharmacoat 615, PEG 4000, titanium dioxide, lactose, polyvinyl pyrrolidone, magnesium stearate and tapioca starch.

#### -MAL number:

MAL20020484A

#### **Manufacturer**

Siam Bheasach Co., Ltd.,  
123 Soi Chokechairuammitr,  
Vibhavadi-Rangsit Road,  
Chatuchak, Bangkok 10900 and  
9 Soi Chokechairuammitr 3,  
Vibhavadi-Rangsit Road,  
Dindang, Bangkok 10400,  
Thailand.

#### **Product Registration Holder**

SPG Pharma (Malaysia) Sdn.  
Bhd.,  
Suite 1701, Block A,  
Damansara Intan e-Business  
Park, No. 1, Jalan SS20/27,  
47400 Petaling Jaya, Selangor  
Darul Ehsan, Malaysia.

#### **Date of revision**

18/01/2016

#### **Serial Number:**

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