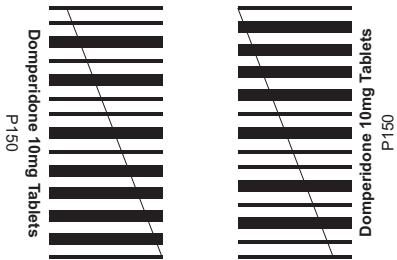


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PACKAGE LEAFLET: INFORMATION FOR THE USER
Domperidone 10mg Tablets
(domperidone maleate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- In this leaflet:**
1. What Domperidone Tablets are and what they are used for
 2. Before you take Domperidone Tablets
 3. How to take Domperidone Tablets
 4. Possible side effects
 5. How to store Domperidone Tablets
 6. Further information

1. WHAT DOMPERIDONE TABLETS ARE AND WHAT THEY ARE USED FOR

Domperidone Tablets contain domperidone as the active ingredient, which belongs to a group of medicines called 'dopamine antagonists'.

Domperidone works by helping to move food faster through your food pipe (oesophagus), stomach and gut. This is so that it does not stay in the same place for too long. It also helps stop food flowing the wrong way back up your food pipe. This medicine is for use in adults and children aged 16 years and over.

Domperidone Tablets are used:

- To treat short lived episodes **nausea** (feeling sick) or **vomiting** (being sick) of less than 48 hours duration.
- To relieve **nausea, fullness, belching, heavy bloated stomach, trapped wind and heartburn** which can happen after a meal for treatment periods of up to 2 weeks. This may be because the stomach's digestive rhythm has slowed down and is not moving food contents in the right direction through the digestive system as efficiently as it needs to.

2. BEFORE YOU TAKE DOMPERIDONE TABLETS

Do Not take Domperidone Tablets if :

You are allergic (hypersensitive) to domperidone or any of the other ingredients in the tablets. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- You have black, tarry bowel motions (stools) or notice blood in your bowel motions. This could be a sign of bleeding in the stomach or intestines
- You have a blockage or tear in your intestines
- You have a tumour of the pituitary gland called a prolactinoma.

Do not take domperidone tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Take Special care with Domperidone and check with your doctor or pharmacist before taking this medicine if:

- You have kidney problems. If you take domperidone over a long period, your doctor may want to lower the amount you use. This will depend on how severe your kidney problems are
- You have liver problems

Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30mg per day. Domperidone should be used at the lowest effective dose in adults and children.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Domperidone. Do this even if they have applied in the past.

Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

In particular, tell your doctor if you are taking any of the following:

- Ketoconazole tablets or liquid for fungal infections.
- Antibiotics for infections (such as erythromycin)

Children under 16 years old:

Do not give Domperidone tablets to children under 16 years old.

Taking Domperidone Tablets with food and drink

The tablets should be taken before meals.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking Domperidone tablets if:

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding. It is best not to take Domperidone tablets if you are breast-feeding. This is because small amounts may pass into the mother's milk.

Driving and using machines

You may feel sleepy, confused or have less control over your movements while taking Domperidone tablets. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Domperidone Tablets

The product contains **lactose** – if you know you have an intolerance to some sugars, tell your doctor before use.

3. HOW TO TAKE DOMPERIDONE TABLETS

Always take Domperidone Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For **oral use** only.

The tablets must be swallowed with a glass of water.

Take the tablets 15 to 30 minutes before meals and, if needed, before you go to bed. Do not crush or chew them.

Adults and children 16 years and over


To treat nausea (feeling sick) and vomiting (being sick) of less than 48 hours duration

Adults and children aged 16 years and over:

Take one tablet up to 3 times a day and one tablet at night.

- Do not take more than 4 tablets in any 24 hour period.
- If your symptoms get worse or the tablets have no effect, talk to your doctor.
- If symptoms of nausea and vomiting persist for more than **48 hours**, talk to your doctor.

A/s: 280 x 240 mm

<div></div>		Product Name	Component	Item Code	Supersede Code	Date & Time
		Domperidone10 mg	Leaflet	P150—	P1504939	14.05.2012 & 2.30 pm
		Customer/Country	Version No.		Reason of Issue	Reviewed / Approved by
		Milpharm (UK)	01		NEW	Sign & Date
Team Leader	Manjunath	Dimensions	Colours :			
Initiator	Ritesh	280 x 240 mm				
Artist	Vision Graphic	Pharmacode				
Additional Information :		-----				

Adults and children 16 years and over
To treat stomach discomfort and nausea experienced after food and drink for up to 2 weeks

Adults and children aged 16 years and over

Take **one tablet** up to 3 times a day and one tablet at night.

- Do not take more than 4 tablets in any 24 hour period.
- If your symptoms get worse or the tablets have no effect, talk to your doctor.
- If your symptoms of stomach discomfort which occurs after a meal persist for more than **2 weeks**, talk to your doctor.

If you take more Domperidone Tablets than you should

If you or someone else swallows too many tablets, contact your doctor, pharmacist or nearest hospital casualty department immediately. Always take any tablets left over with you, this leaflet and also the box, as this will allow easier identification of the tablets.

The signs of taking more than you should include feeling sleepy, confused, uncontrolled movements (especially in children) which include unusual eye movements, unusual movements of the tongue or abnormal posture (such as a twisted neck).

If you forget to take Domperidone Tablets

If you miss a dose, take it as soon as you remember and carry on as before. If it is almost time for your next dose, skip the forgotten dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Domperidone Tablets can have side effects, although not everybody gets them.

Stop taking Domperidone tablets and see your doctor or go to a hospital straightaway if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria).This may mean you are having an allergic reaction to Domperidone tablets.
- You notice uncontrolled movements. These include irregular eye movements, unusual movements of the tongue, and abnormal posture such as a twisted neck, trembling and muscle stiffness. This is more likely to happen in children. These symptoms should stop once you stop taking Domperidone tablets.
- You have a very fast or unusual heartbeat. This could be a sign of a life-threatening heart problem.

Other side effects include:

Common (less than 1 in 10 people)

- Dry mouth.

Uncommon (less than 1 in 100 people)

- Anxiety.
- Loss of interest in sex or diminished interest in sex.
- Sleepiness or headache.
- Diarrhoea.
- Rash or itchiness
- Painful or tender breasts, or discharge from breasts
- A general feeling of weakness.

Other side effects which occur but it is unknown how often:

- Hives.
- Agitation or Nervousness.

- Eye movement disorder.
- Inability to urinate.
- Swollen breasts (even in men).
- Stop in menstrual periods.
- Changes in certain laboratory test results. If you have a blood test to check your liver function tell your doctor or nurse that you are taking Domperidone.

Side effects such as feeling drowsy, nervous, agitated or irritable or having a fit are more likely to happen in children.

Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30mg per day. Domperidone should be used at the lowest effective dose in adults and children.

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

5. HOW TO STORE DOMPERIDONE TABLETS

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original package.

Do not use the tablets after the expiry date is stated on the label.

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.

6. FURTHER INFORMATION

What Domperidone Tablets contain

The **active** substance is domperidone maleate, 10mg per tablet. The **other** ingredients are microcrystalline cellulose, lactose monohydrate, maize starch, povidone K30, sodium lauryl sulphate, silica colloidal anhydrous, magnesium stearate (*see Section 2 'Important information about some of the ingredients of Domperidone Tablets'.*)

What Domperidone Tablets looks like and contents of the pack

The tablets are white, round, biconvex and uncoated with “Dm 10” marked on one side. They are available in blister packs of 30 and 100 tablets.

Marketing Authorisation Holder:

Milpharm Limited
Ares, Odyssey Business Park,
West End Road,
South Ruislip, HA4 6QD,
United Kingdom

Manufacturers:

Milpharm Limited
Ares, Odyssey Business Park,
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South Ruislip, HA4 6QD
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