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PACKAGE LEAFLET: INFORMATION FOR THE USER

Domperidone 10mg Film-Coated 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 while you are receiving your treatment.
- If you have any further questions, please ask your doctor or nurse.
- This medicine has been prescribed for you. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get 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 10mg Film-Coated Tablets are and what they are used for
2. Before you take Domperidone 10mg Film-Coated Tablets
3. How to take Domperidone 10mg Film-Coated Tablets
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6. Further information

1. What Domperidone 10mg Film-Coated Tablets are and what they are used for

The name of your medicine is Domperidone 10mg Film-Coated Tablets. Domperidone is an anti-emetic which can stop you feeling sick. The active ingredient is domperidone maleate.

Each tablet contains 10mg domperidone as domperidone maleate.

Domperidone is used to treat

- nausea and vomiting
- indigestion or a feeling of discomfort or fullness in the stomach.

2. Before you take Domperidone 10mg Film-Coated Tablets

Important information about some of the ingredients in your medicine

- If you have been told by your doctor that you have an intolerance to some sugars, check with your doctor before taking Domperidone 10mg Film-Coated Tablets.
- This medicinal product contains 0.97 mmol (0.042 mg) of sodium per tablet. To be taken into consideration by patients on a controlled sodium dose.

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.

Do not take Domperidone 10mg Tablets if you

- have ever had an allergic reaction to domperidone or any of the other ingredients listed in section 6, Further Information.
- have or think you may have a serious intestinal problem such as internal bleeding (symptom being persistent black bowel motions), or an obstruction or perforation of the stomach or intestine (usually this involves severe stomach cramps).
- suffer from a tumour of the pituitary gland called

- prolactinoma.
- have liver problems

Domperidone 10mg Film-Coated Tablets should not be given to children weighing less than 35kg.

Before you use Domperidone 10mg Film-Coated Tablets tell your doctor if you

- have a kidney disorder.
- are pregnant, or likely to become pregnant.
- are breast-feeding.

Driving and using machinery

You may have less control over your movements whilst taking Domperidone Tablets. If this happens do not drive or use any tools or machines.

Taking other medicines

Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicine, even those not prescribed by a doctor.

If taken with other medicines the effect of Domperidone 10mg Tablets or the effects of the other medicine may be altered.

Examples of medicines that can affect domperidone are:

- Opioids, used to treat pain or as an analgesic
- ketonazole, used to treat fungal infections
- ritonavir, used to treat virus infections
- erythromycin, used to treat bacterial infections

If you have any doubts about whether you should take this medicine then talk to your doctor.

3. How to take Domperidone 10mg Film-Coated Tablets

These tablets have been prescribed for you by a doctor. Take them exactly as he or she has told you. Please read the label carefully. The tablets should be swallowed whole with a sufficient quantity of liquid (e.g. one glass of water).

Adults

The usual dose for nausea and vomiting in adults is 10-20mg (1-2 tablets) three to four times a day.

Children

Children weighing less than 35kg (5½ stone) should not take these tablets.

The usual dose for the treatment is 0.25 - 0.5mg per kg bodyweight taken three to four times a day.

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**WOCKHARDT
CREATIVE UNIT**

ARTWORK CHECK BOX

PRODUCT :	Domperidone Maleate 10mg - 30 & 100 Tabs
CUSTOMER :	Wockhardt UK
FP CODE :	FP2014; FP2016
PLANT LOCATION :	L1
DIMENSIONS :	(w)148 x (h)210mm
PHARMACODE No. :	2241
SAP CODE No. :	214530
TEXT FONT SIZE :	7 pt.
FILE NAME :	Domperidone_Leaflet_104110-3.ai
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CHANGE CONTROL : Version changes due to change in:
 Size/Layout Regulatory Non-Regulatory
 Changes in detail:
 • New regulatory text (as requested by WUK)
 • Arrow indicating direction of pharmacode reading
 • Removed pre-printed neutral code
 • Pharmacode positioned at 5mm from the cutting edge

Your pharmacist may be able to help you if you are not sure.

You should not take the tablets for more than four weeks without consulting your doctor.

The dose should be reduced for patients with severe kidney problems and reviewed regularly by your doctor.

Your doctor may advise you to take your medicine in a different way, so you should always follow your doctor's advice about how and when to take your medicine and always read the label. If you feel that the effect of Domperidone 10mg Film-Coated Tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more Domperidone 10mg Tablets than you should

If you accidentally take too many tablets you should contact your doctor, pharmacist or nearest hospital casualty department immediately. Take this leaflet and any tablets you have left to show the doctor or pharmacist

If you forget to take your tablets

Take your tablets as soon as you remember. If it is almost time for your next dose, wait until that is due and continue as normal. Do not take a double dose to make up for the forgotten dose.

4. Possible side effects

Like all medicines, Domperidone 10mg Film-Coated Tablets can have side effects.

Very rarely patients have experienced allergic reactions to Domperidone.

If any of the following reactions occur, STOP taking your Domperidone 10mg Film-Coated Tablets and either tell your doctor immediately or go to your nearest hospital:

- Palpitations or dizziness or changes to heart traces (ECG) indicating a heart problem
- Facial or neck swelling, flushing or fainting
- Problems with breathing including shortness of breath and wheezing
- Rash and itching (hives) or nettle rash (urticaria)
- Other allergic reactions such as anaphylactic reaction and shock
- Uncontrolled movements of the limbs and face, including the eyes (twitching)
- In exceptional cases mild stomach cramps can occur, but these should go away quickly.

Other side effects include:

Uncommon (affects less than 1 in 100 people)

- Breast pain

Rare (affects less than 1 in 1,000 people)

- Reduced libido
- Unusual production of breast milk in men and women
- Disruption of menstrual flow
- Breast growth in men

Very rare (affects less than 1 in 10,000 people)

- Agitation
- Nervousness
- Abnormal movements (muscle spasms causing twisting or repetitive movements)
- Convulsions (fits)
- Drowsiness
- Headache

- Diarrhoea
- Abnormal liver function test

Domperidone 10mg Tablets may be associated with an increased risk of heart rhythm disorder and cardiac arrest.

Side effects more likely to occur in children include convulsions (fits) agitation and drowsiness.

Stop taking Domperidone 10mg Tablets and tell your doctor as soon as possible if you experience any of the above very rare side effects.

If you notice any side effects not mentioned in this leaflet, or if you suffer from any of the side effects listed please inform your doctor or pharmacist.

5. How to store Domperidone 10mg Film-Coated Tablets

- Keep out of the reach and sight of children.
- Do not use your Domperidone 10mg Tablets after the expiry date printed on the package.
- If you have any tablets that are out of date, please return them to your pharmacist for disposal.
- Do not store above 25°C. Store the tablets in the original package. Do not transfer Domperidone 10mg Film-Coated tablets to another container.

6. Further information

Domperidone 10mg Film-Coated tablets are white, circular, film coated tablets marked DM on one face, 10 on the reverse. The active ingredient is domperidone maleate.

Other ingredients in your tablets are lactose, pregelatinised maize starch, microcrystalline cellulose, sodium starch glycolate, magnesium stearate and Opadry white OY-S-28899 which consists of hypromellose, titanium dioxide (E171) and macrogol.

Domperidone 10mg Tablets are available in cartons of 30 or 100 tablets.

Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.
Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only). Please be ready to give the following information:

Product name	Reference number
Domperidone 10mg Film-Coated Tablets	29831/0076

This is a service provided by the Royal National Institute of Blind People.

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