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PACKAGE LEAFLET:
INFORMATION FOR THE USER
DOMPERIDONE TABLETS
10 mg
[Domperidone Maleate]

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Domperidone Tablets are and what they are used for
2. What you need to know before you take Domperidone Tablets
3. How to take Domperidone Tablets
4. Possible side effects
5. How to store Domperidone Tablets
6. Contents of the pack and other information

1. What Domperidone Tablets are and what they are used for

The active ingredient in Domperidone Tablets is domperidone which belongs to 'dopamine antagonists' medicines group.

This medicine is used in adults and children to treat nausea (feeling sick) and vomiting (being sick) in adults and adolescents (12 years of age and older and weighing 35 kg or more).

2. What you need to know before you take Domperidone Tablets

Do not take Domperidone if:

- you are allergic to domperidone or any of the other ingredients of this medicine (listed in section 6)
- you have a disease or tumour of the pituitary gland (prolactinoma)
- you have severe tummy cramps or pain, or persistent black, tarry stools or blood in the stool
- you have a blockage or tear in your intestines
- you have a moderate or severe liver disease
- you have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure)
- your ECG (electrocardiogram) shows a heart problem called "prolonged QT corrected interval"
- you have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood
- you are taking certain medicines (see Other medicines and Domperidone Tablets).

Warnings and precautions

Before taking this medicine contact your doctor if you:

- suffer from liver problems (liver function impairment or failure) (see "Do not take Domperidone Tablets")
- suffer from kidney problems (kidney function impairment or failure). It is advisable to ask your doctor for advice in case of prolonged treatment as you may need to take a lower dose or take this medicine less often, and your doctor may want to examine you regularly.

Domperidone may be associated with an increased risk of heart rhythm disorder and cardiac arrest. The risk may be more likely in those over 60 years old or taking doses higher than 30mg per day. The risk also increases when domperidone is given together with some drugs.

Tell your doctor or pharmacist if you are taking drugs to treat infection (fungal infections or bacterial infection) and/or if you have heart problems or AIDS/HIV (see section Other medicines and Domperidone).

While taking domperidone, contact your doctor if you experience heart rhythm disorders such as palpitations, trouble breathing, loss of consciousness. Treatment with domperidone should be stopped.

Adolescents weighing less than 35 kg and children

Domperidone should not be given to adolescents 12 years of age and older weighing less than 35 kg, or in any children less than 12 years of age, as it is not effective in these age groups.

Other medicines and Domperidone Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Domperidone Tablets if you are taking medicine to treat:

- fungal infections such as azole anti-fungals, specifically oral ketoconazole, fluconazole or voriconazole
- bacterial infections, specifically erythromycin, clarithromycin, telithromycin, moxifloxacin, pentamidine (these are antibiotics)
- heart problems or high blood pressure (e.g. amiodarone, dronedarone, quinidine, disopyramide, dofetilide, sotalolol, diltiazem, verapamil)
- psychoses (e.g. haloperidol, pimozide, sertindole)
- depression (e.g. citalopram, escitalopram)
- gastro-intestinal disorders (e.g. cisapride, dolasetron, prucalopride)
- allergy (e.g. mequitazine, mizolastine)
- malaria (e.g. in particular halofantrine)
- AIDS/HIV (protease inhibitors)
- cancer (e.g. toremifene, vandetanib, vincamine).

Tell your doctor or pharmacist if you are taking drugs to treat infection, heart problems or AIDS/HIV.

Tell your doctor if you are taking:

- Bromocriptine to treat patient with high levels of the hormone prolactin in the blood
- Opioid analgesics as pain killers (e.g. morphine, codeine, methadone, pethidine)
- Anti-muscarinics to treat disorders of the gut and digestive system (e.g. atropine, mebeverine, hyoscine, propantheline).

Domperidone Tablets and apomorphine

Before you use Domperidone Tablets and apomorphine, your doctor will ensure that you tolerate both medicines when used simultaneously. Ask your doctor or specialist for a personalised advice. Please refer to the apomorphine leaflet.

It is important to ask your doctor or pharmacist if Domperidone Tablets are safe for you when you are taking any other medicines, including medicines obtained without a prescription.

Taking Domperidone Tablets with food and drink

It is recommended to take this medicine before meals, as when taken after meals the absorption of the medicine is slightly delayed.

Pregnancy:

If you are pregnant or think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding:

Small amounts of domperidone have been detected in breast milk. Domperidone may cause unwanted side effects affecting the heart in a breast-fed baby. Domperidone should be used during breast feeding only if your physician considers this clearly necessary. Ask your doctor for advice before taking this medicine.

Driving and using machines:

At normal doses, Domperidone does not affect your ability to drive or use machines. If you notice symptoms of drowsiness, confusion, impaired awareness and lack of co-ordination do not drive or operate machines.

Domperidone Tablets contain sodium:

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

Domperidone Tablets contain lactose:

These tablets contain lactose.

They may not be suitable for patients with lactose intolerance (inability to digest lactose, which is sugar found in milk and milk products), galactosaemia or

glucose/galactose malabsorption (inability to digest carbohydrates and sugars which are found in many foods including starches, milk and milk products).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Domperidone Tablets

Follow these instructions closely unless your doctor has told you otherwise.

Duration of treatment:

Symptoms usually resolve within 3-4 days of taking this medicine. Do not take Domperidone Tablets for longer than 7 days without consulting your doctor.

Adults and adolescents 12 years of age and older with a body weight of 35 kg or more:

Domperidone Tablets should be taken whole with a glass of water, by mouth.

The usual dose is one tablet taken up to three times per day, if possible before meals.

Do not take more than three tablets per day.

If you have kidney problems your doctor may tell you to take a lower dose, less often.

If you take more Domperidone Tablets than you should:

If you have used or taken too much Domperidone, contact your doctor, pharmacist or the poison centre immediately, in particular if a child has taken too much. Take the carton and any tablets left with you. This is so the doctors know what you have taken.

In the event of an overdose, symptomatic treatment could be implemented. An ECG monitoring could be undertaken, because of the possibility of a heart problem called prolonged QT interval.

If you have taken too much Domperidone you may also experience sleepiness, confusion, uncontrolled movements, such as irregular eye movements or abnormal posture, such as a twisted neck.

If you forget to take Domperidone Tablets:

Take your medicine as soon as you remember.

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

How long can I take this medicine for?

You should not take this medicine for longer than 7 days without talking to your doctor.

4. Possible side effects

Like all medicines, Domperidone Tablets can cause 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.
- You notice any 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.
- You have a very fast or unusual heartbeat. This could be a sign of a life-threatening heart problem.
- You have a fit (seizure).

Common (affects less than 1 in 10 people):

- Dry mouth

Uncommon (affects less than 1 in 100 people):

- Feeling anxious
- Lowering of sexual drive (libido) in men
- Feeling drowsy
- Headaches
- Diarrhoea
- Itchy skin. You may also have a rash
- Unusual production of breast milk in men and women
- Painful or tender breasts
- A general feeling of weakness.

Not known (Frequency cannot be estimated from the available data)

- Disorders of the cardiovascular system: heart rhythm disorders (rapid or irregular heart beat)

have been reported; if this happens, you should stop the treatment immediately. 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 30 mg per day. Domperidone should be used at the lowest effective dose in adults and children.

- Feeling agitated or irritable
- Feeling more nervous than usual
- Abnormal eye movements
- Inability to urinate
- Breast enlargement in men
- In women, menstrual periods may be irregular or stop
- A blood test shows changes in the way your liver is working.

Some patients who have used Domperidone for conditions and dosages requiring longer term medical supervision have experienced the following unwanted effects:

Restlessness; swollen or enlarged breasts, unusual discharge from breasts, irregular menstrual periods in women, difficulty breast-feeding, depression, hypersensitivity.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Domperidone Tablets

Keep out of the sight and reach of children. Do not store above 30°C.

Do not use Domperidone Tablets after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not use Domperidone Tablets if you notice visible signs of deterioration.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information What Domperidone Tablets contains

The active substance is Domperidone Maleate BP/ Ph Eur.

The other ingredients are:

- Lactose/ lactose monohydrate
- Maize starch
- Microcrystalline cellulose (Avicel PH 102)
- Povidone (K-30)
- Sodium lauryl sulphate/sodium laurilsulfate
- Colloidal anhydrous silica
- Magnesium stearate (Vegetable).

What Domperidone Tablets look like and contents of the pack

Description: White, round, biconvex tablets marked "Dm 10" on one side and plain on the other side.

Contents of the pack:

10 tablets in a blister, 3 blisters in a carton. 10 tablets in a blister, 10 blisters in a carton.

Marketing Authorisation Holder Strides Pharma UK Ltd.

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L658

150 x 300 mm

Front Side Printing

150 x 300 mm

Back Side Printing

ARTWORK DETAIL LABEL

Product	Domperidone 10mg		
Buyer/Country	SPUK	Component	Pack Insert
Dimension	150 x 300 mm	Pack	--
New Item Code	1040336	Old Item Code	1039782
Colour Shades	██████ BLACK	No. of Colours	1

Change Control No.	PC-ODF/2018/601 - Record Number: 174267 - (also Annexure)	Artwork Version	9.0
Design/Style	Front & Back Printing. To be supplied in the unfolded size.		
Substrate	60 GSM Paper.		
Special Instructions	Printing clarity to be clear & sharp.		
Autocartanator Requirements	Pack insert supply should be as per auto-cartanator. Refer auto-cartanator drawing for instructions.		
Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.			

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