



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

## **MEPRASIL-D CAPSULES**

Omeprazole 20mg and Domperidone 10mg

### **Read all this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

### **In this leaflet**

1. What Meprasil-D capsules is and what it is used for.
2. What you need to know before you take Meprasil-D capsules.
3. How to take Meprasil-D capsules.
4. Possible side effects.
5. How to store Meprasil-D capsules.
6. Contents of the pack and other information.

### **1. WHAT MEPRASIL-D CAPSULES IS AND WHAT IT IS USED FOR**

Meprasil-D capsules contains Omeprazole 20mg and Domperidone 10mg as active ingredients. Omeprazole belongs to a group of medicines called proton-pump inhibitors. They work by reducing the amount of acid that your stomach produces while Domperidone belongs to a group of medicines called 'dopamine antagonists'. Domperidone is used to treat nausea (feeling sick) and vomiting (being sick).

### **2. WHAT YOU NEED TO KNOW BEFORE TAKING MEPRASIL-D CAPSULES**

#### **Do not take this medicine if:**

- If you are allergic to Omeprazole or any of the other ingredients of Omeprazole capsules.
- If you are allergic to medicines containing other proton pump inhibitors (e.g. Pantoprazole, Lansoprazole, Rabeprazole, Esomeprazole).
- If you are taking a medicine containing Nelfinavir (used for HIV infection).
- If you are allergic (hypersensitive) to Domperidone or any of the other ingredients of Domperidone 10mg capsules.
- If 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.
- If you have a blockage or tear in your intestines.
- If you have a tumour of the pituitary gland (prolactinoma).
- If you have a moderate or severe liver disease.
- If your ECG (electrocardiogram) shows a heart problem called "prolonged QT corrected interval"
- If 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).
- If you have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood.

### **Warnings and precautions**

#### **Talk to your doctor or pharmacist before taking this medicine if:**

- You suffer from liver problems (liver function impairment or failure) (see "Do not take Domperidone Capsules if")
- You 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



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

## **MEPRASIL-D CAPSULES**

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- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools.
- You experience persistent or severe diarrhoea.
- You have ever had a skin reaction after treatment with a medicine similar to omeprazole capsules that reduces stomach acid.
- You lose a lot of weight for no reason and have problem swallowing.

### **Driving and using machines**

Meprasil-D does not affect your ability to drive or use machines.

### **Pregnancy and breast-feeding**

Talk to your doctor or pharmacist before taking Meprasil-D capsules if:

You are pregnant, might become pregnant or think you may be pregnant and are breast-feeding. It is best not to take Meprasil-D capsules if you are breast-feeding. Small amounts of Meprasil-D have been detected in breast milk. Meprasil-D may cause unwanted side effects affecting the heart in a breastfed baby. Meprasil-D should be used during breast feeding only if your physician considers this clearly necessary.

### **3. HOW TO TAKE MEPRASIL-D CAPSULES**

Your doctor will decide how long you will need to take this medicine. Symptoms usually resolve within 3-4 days of taking this medicine. Do not take Meprasil-D capsules for longer than 7 days without consulting your doctor.

#### **Taking this medicine**

- Swallow the capsules whole with a drink of water.
- Take the capsules 15 to 30 minutes before a meal.
- Do not crush or chew them

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

The usual dose is one capsule taken up to two times a day, if possible before meals. Do not take more than two capsules per day or as directed by a Physician.

*This product is not suitable for children under 12 years of age and older with a body weight of less than 35kg.*

#### **People with kidney problems**

Your doctor may tell you to take a lower dose or to take the medicine less often.

#### **If you take more Meprasil-D capsules than you should**

If you have used or taken too many Meprasil-D capsules, contact your doctor, pharmacist, or the poisons centre at your nearest hospital casualty department immediately. Take the carton and any capsules left with you. This is so the doctors know what you have taken.

In the events of overdose, symptomatic treatment could be implemented. An ECG monitoring could be undertaken, because of the possibility of heart problem called prolonged QT interval. The signs of taking more than you should include feeling sleepy, confused, uncontrolled movements which include unusual eye movements, unusual movements of the tongue or abnormal posture (such as a twisted neck).

#### **If you forget to take Meprasil-D capsules**

If you forgot to take Meprasil-D capsules, take it as soon as you remember. However, if it is



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

## **MEPRASIL-D CAPSULES**

Omeprazole 20mg and Domperidone 10mg

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 a forgotten dose.

#### **4. POSSIBLE SIDE EFFECTS OF MEPRASIL-D CAPSULES**

Like all medicines, Meprasil-D capsules can have side effects, although not everybody gets them. Stop taking Meprasil-D capsules 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 Meprasil-D capsules.
- 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. These symptoms should stop once you stop taking Meprasil-D capsules.
- You have a very fast or unusual heartbeat. This could be a sign of a life-threatening heart problem.
- You have a fit (seizure).

**Other side effects include:**

**Common (may affect up to 1 in 10 people):**

- Dry mouth

**Uncommon (may affect up to 1 in 100 people):**

- Lowering of sexual drive (libido) in men
- Feeling anxious
- 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 heartbeat) 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. Meprasil-D capsules should be used at the lowest effective dose.
- Feeling agitated or irritable
- Feeling more nervous than usual
- Abnormal eye movements
- Inability to urinate
- Breast enlargement in men
- In women, menstrual periods may stop or become irregular
- A blood test shows changes in the way your liver is working. Some patients who have used Meprasil-D capsules 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 breastfeeding, depression, hypersensitivity.



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

## MEPRASIL-D CAPSULES

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### Reporting of side effects

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

### HOW TO STORE MEPRASIL-D CAPSULES

- Keep all medicines out of the reach of children.
- Do not use this medicine after the expiry date which is stated on the carton after 'Exp. Date' used for expiry date. The expiry date refers to the last day of that month.
- Store below 30°C, in a dry place.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 5. FURTHER INFORMATION

### What Meprasil-D Capsules contains




Meprasil-D contains Omeprazole 20mg and Domperidone 10mg.

### What Meprasil-D Capsules look like and contents of the pack

Meprasil-D is presented as 2x10 and 10x10 capsules in Alu-Alu blisters, placed in a carton with insert.

### SUPPLIER AND MANUFACTURER

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