

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

### **Omeprazole Delayed Release Capsules USP 20mg- OMESK**

Read all of this leaflet carefully before you starts giving 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, health care worker or pharmacist.
- Do not pass it on to others. It may harm them, even if their symptoms are the same.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care worker or pharmacist

In this leaflet:

- 1. What Omeprazole Delayed Release Capsules USP 20mg- OMESK are and what they are used for**
- 2. What you need to know before you take Omeprazole Delayed Release Capsules USP 20mg- OMESK**
- 3. How to Omeprazole Delayed Release Capsules USP 20mg- OMESK**
- 4. Possible side effects**
- 5. How to store your Omeprazole Delayed Release Capsules USP 20mg- OMESK**
- 6. Contents of the pack and other information**

#### **1. WHAT OMEPRAZOLE DELAYED RELEASE CAPSULES USP 20MG- OMESK ARE AND WHAT THEY ARE USED FOR**

Omeprazole capsules contain the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'.

They work by reducing the amount of acid that your stomach produces.

Omeprazole is used to treat the following conditions:.

##### Duodenal Ulcer (adults):

Omeprazole delayed-release capsules is indicated for short-term treatment of active duodenal ulcer in adults. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

### Treatment of Gastroesophageal Reflux Disease (GERD) Symptomatic GERD

Omeprazole delayed-release capsules are indicated for the treatment of heartburn and other symptoms associated with GERD.

### Erosive Esophagitis

Omeprazole delayed-release capsules are indicated for the short-term treatment (4-8 weeks) of erosive esophagitis that has been diagnosed by endoscopy.

The efficacy of omeprazole delayed-release capsules used for longer than 8 weeks in these patients has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of erosive esophagitis or GERD symptoms. (eg, heartburn), additional 4-8 week courses of omeprazole may be considered.

### Maintenance of Healing of Erosive Esophagitis (adults and pediatric patients)

Omeprazole delayed-release capsules are indicated to maintain healing of erosive esophagitis in pediatric patients and adults.

Controlled studies do not extend beyond 12 months.

### Pathological Hypersecretory Conditions (adults)

Omeprazole delayed-release capsules are indicated for the long-term treatment of pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome, multiple endocrine adenomas and systemic mastocytosis)

## **2. What you need to know before you take Omeprazole Delayed Release Capsules USP 20mg-OMESK**

- Do not take Omeprazole capsules and tell your doctor if you:
- are allergic to omeprazole or any of the other ingredients of this medicine
- are allergic to medicines containing other proton pump inhibitors(e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- are taking a medicine containing nelfinavir (used for HIV infection)

If you are not sure, talk to your doctor or pharmacist before taking Omeprazole.

Warnings and precautions talk to your doctor before taking Omeprazole capsules

Omeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Omeprazole or while you are taking it, talk to your doctor straight away if:

- you lose a lot of weight for no reason and have problems swallowing.

- you get stomach pain or indigestion.
- you begin to vomit food or blood.
- you pass black stools (blood-stained faeces).
- you experience severe or persistent diarrhoea , as omeprazole has been associated with a small increase in infectious diarrhoea.
- You have severe liver problems.
- you have ever had a skin reaction after treatment with a medicine similar to Omeprazole Capsules that reduces stomach acid.
- you get a rash on your skin , especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Omeprazole Capsules.

Remember to also mention any other ill-effects like pain in your joints

- you take atazanavir
- your body does not absorb vitamin B12(cobalamin)very well
- you are due to have a specific blood test (Chromogranin A)

Taking a proton pump inhibitor like Omeprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine.

Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis). Your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

### **3. How to take Omeprazole Delayed Release Capsules USP 20mg- OMESK**

As directed by physician. Omeprazole capsules should be swallowed whole and not opened, chewed or crushed.

### **4. Possible side effects**

Like all medicines, this medicine can cause side-effects although not everybody gets them.

- Like all medicines, this medicine can cause side effects, although not everybody gets them.
- If you notice any of the following rare but serious side effects, stop taking Omeprazole and contact a doctor immediately:
- Rare side effects (may affect up to 1 in 1,000 people)  
Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Very rare side effects (may affect up to 1 in 10,000 people)

Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be ‘erythema multiforme’, ‘Stevens-Johnson syndrome’ or ‘toxic epidermal necrolysis’.

- Yellow skin, dark urine and tiredness which can be symptoms of liver failure.
- Shortness of breath, tiredness, dizziness, bleeding or bruising may be caused by a reduction in red, white blood cells and platelets (pancytopenia). A blood test may be required.
- Omeprazole may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.
- Side effects may occur with certain frequencies, which are defined as follows:
- Tell your doctor if you notice any of the following side effects or notice any other effects not listed:
- Common side effects (may affect up to 1 in 10 people)  
Headache.  
Diarrhoea, stomach pain, constipation, wind (flatulence).  
Feeling sick (nausea) or being sick (vomiting). Benign polyps in the stomach.

## **5. How to store Omeprazole Delayed Release Capsules USP 20mg- OMESK**

Store between 15<sup>0</sup>C to 30<sup>0</sup>C. Protect from light.

Keep the medicine out of reach of children.

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

## **6. Contents of the pack and other information**

What Omeprazole Delayed Release Capsules USP 20mg- OMESK contain:

Each capsule contains Omeprazole USP.

**What Omeprazole Delayed Release Capsules USP 20mg- OMESK looks like and contents of the pack:**

**Omeprazole Delayed Release Capsules USP 20mg- OMESK** is Plain Hard gelatin capsules of size "2" having Pink CAP and White BODY without any spots on the surface. Containing white to off white Enteric coated Omeprazole pellets.

They are packaged in strip pack of 10 capsule, 10 strips packed in a printed carton with a printed insert.

**Manufactured by:**

The logo for S Kant Healthcare Ltd. features a stylized 'SK' monogram to the left of the text 'S Kant' in a large, bold, sans-serif font. Below 'S Kant' is the text 'HEALTHCARE Ltd.' in a smaller, all-caps, sans-serif font.

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