Omeprazole

Omepron®

20 mg Capsule

PROTON PUMP INHIBITOR

FORMULATION

Each capsule contains: Omeprazole…..20 mg

PRODUCT DESCRIPTION

Omeprazole (Omepron®) 20 mg comes in a hard gelatin capsule with an opaque pink body and an opaque reddish-brown cap. Each capsule is marked with "STD 516" on both body and cap and contains white to off-white pellets.

WHAT IS IN THE MEDICINE?

This medicine contains omeprazole which works by decreasing the amount of acid produced in the stomach.

STRENGTH OF THE MEDICINE

Please see formulation.

WHAT IS THE MEDICINE USED FOR?

Omeprazole is used for the short-term treatment and symptomatic relief of heartburn that occurs two or more days per week (frequent heartburn).

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Adult dose: Orally (by mouth), 1 capsule once a day 30 minutes to 1 hour before breakfast with a full glass of water

Take the medicine for 14 days. Or, as directed by a doctor.

- Do not take more than 20 mg (1 capsule) per day.
- Do not take a 14-day course more often than every 4 months unless directed by a doctor.
- Capsules should be swallowed whole. Do not split, crush or chew.
- For children under 18 years old, ask a doctor.

Alternative Administration Option:

For patients who are unable to swallow the capsule whole, the capsule may be opened and the contents swallowed directly with a half glass of liquid or after mixing with a slightly acidic fluid such as applesauce, fruit juice and yoghurt or in non- carbonated water. The mixture should be taken immediately and should not be stored for future use. The pellets must not be chewed or crushed.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- If you are allergic to omeprazole, other proton pump-inhibitors (e.g., lansoprazole, pantoprazole, rabeprazole, etc.) or any ingredient in this product.
- If you have trouble or pain swallowing food, vomiting with blood or bloody or black stools. These may be due to a serious condition and require consultation with your doctor.
- Omeprazole may take 1 to 4 days to achieve its full effect. Therefore, it is not used for the immediate relief of heartburn symptoms or prevention of an occasional heartburn due to consumption of certain food or drinks.

UNDESIRABLE EFFECTS

Omeprazole is generally well tolerated. Most undesirable effects have been mild and temporary and there has been no consistent relationship with the treatment.

Gastrointestinal Effects: Diarrhea, abdominal pain, nausea, vomiting, constipation, gassiness (flatulence), and acid regurgitation are the most common. Discomfort or pain in swallowing, abdominal swelling, loss of appetite, irritable colon, stool discoloration, inflammation of the pancreas (sometimes fatal), fungal infection of the esophagus, mucosal atrophy (decrease in size) of the tongue, taste disorders, dry mouth, and inflammation of the mouth have been reported rarely. Benign stomach polyps have been reported rarely and appear to resolve after discontinuation of omeprazole.

Nervous System Effects: Headache and dizziness are the most common. Weakness has also been reported. Pain, fatigue, feeling of bodily discomfort, vertigo, burning or prickling sensation or numbness of the skin, loss of sensation, and psychic disturbances (including depression, agitation, aggression, hallucinations, reversible mental confusion, sleeplessness, nervousness, muscle shaking, absence of emotion, drowsiness, anxiety, and dream abnormalities) are uncommon and a causal relationship with omeprazole was not established in many cases.

Respiratory Effects: Upper respiratory tract infections, cough, acute respiratory distress syndrome (a life-threatening lung condition that leads to low oxygen levels in the blood), respiratory failure, and pneumothorax (collapsed lung) have been reported. Nosebleed and pharyngeal pain have also been reported.

Administration of proton pump inhibitors may increase the risk of developing certain infections (e.g., community-acquired pneumonia).

Musculoskeletal Effects: Back pain, muscle cramps, muscle aches, muscle weakness, joint pain, and leg pain, rarely.

People who are taking multiple daily doses of proton pump inhibitors for a long period of time may have an increased risk of fractures of the hip, wrist or spine.

Effects on the Liver: Mild, and rarely, marked increases in liver enzymes. Yellowish color of the skin, eyes and other tissues, and other liver problems (e.g., inflammation of the liver, liver failure, hepatic encephalopathy), rarely.

Skin and Allergic Reactions: Rash, dermatitis, itch and/or hives are uncommon. Sensitivity to sunlight, severe skin reactions (e.g., Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis), hair loss, allergic reactions (e.g., fever, angioedema, life-threatening allergic reaction), dry skin, and increased sweating were reported rarely.

Effects on the Blood: Blood disorders (e.g., leukopenia, agranulocytosis, thrombocytopenia, pancytopenia, and anemia), rarely.

Genitourinary Effects: Kidney problems (e.g., inflammation of the kidney), urinary tract infection, urinary frequency, large amounts of sugar in the urine, blood in the urine, protein in the urine, impotence, testicular pain, and breast development in males have been reported rarely.

Cardiovascular Effects: Low blood pressure, high blood pressure, abnormal heart rhythm, slow heart rate, fast heart rate, chest pain, fluid retention, and irregular heartbeat have been reported.

Effects on the Eyes: Blurred vision, irritation of the eyes, dry eye syndrome, decrease in the size of the eyes, anterior ischemic optic neuropathy (disturbance in the function of the brain or spinal cord affecting the nerves of the eyes), inflammation of the optic nerve, and double vision have been reported.

Other Undesirable Effects: Low serum sodium levels, low blood sugar, weight gain, fever, otitis media (infection in the ear) and ringing in the ears have been reported.

Proton pump inhibitors may cause hypomagnesemia (low serum magnesium levels) if taken for prolonged periods of time (in most cases, longer than 1 year). Low serum magnesium levels can result in serious effects including muscle spasm, irregular heartbeat and convulsions; however, patients do not always have these symptoms.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

- Omeprazole taken concomitantly may increase the effects of warfarin (or other vitamin K antagonists), phenytoin, diazepam, digoxin, saquinavir, tacrolimus, and cilostazol. The dose of these drugs should be adjusted when omeprazole therapy is initiated or stopped.
- Omeprazole increases gastric pH and may lessen the effect of ampicillin, iron salts, dasatinib, and antifungal medicines such as ketoconazole and itraconazole.
- Concomitant administration with voriconazole may increase the effects of both omeprazole and voriconazole.
- Rifampicin and St. John's Wort may decrease the effects of omeprazole.
- Omeprazole may decrease the effects of medicines for HIV treatment; atazanivir and nelfinavir should not be used with omeprazole.
- Concomitant use with clopidogrel is not recommended since omeprazole may decrease the effects of clopidogrel.

Tell your doctor about all medicines you are taking including supplements and herbal medicines.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss a dose, just take the next dose as scheduled, i.e., once a day.
Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

Store at temperatures not exceeding 30°C.
Keep the product out of reach and sight of children.

SIGNS AND SYMPTOMS OF OVERDOSAGE

Symptoms of overdosage with omeprazole include confusion, drowsiness, dizziness, blurred vision, fast heart rate, nausea, vomiting, abdominal pain, excessive sweating, flushing, headache, dry mouth, and other undesirable effects similar to those seen in recommended doses.

WHAT TO DO IF YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you have taken more than the recommended dosage, consult a doctor.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

Do not take more than the recommended dose or duration of treatment.

Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Ask a doctor before use if:

- You have suspected stomach ulcer and are awaiting confirmation. Stomach cancer should be excluded first before giving omeprazole or other proton pump inhibitors since they may hide the signs of stomach cancer and delay diagnosis.
- You are pregnant, planning to get pregnant or breastfeeding
- You have liver problems
- You are taking other medicines (see ***What other medicine or food should be avoided while taking this medicine?***)

Ask a doctor before use if you have:

- Had heartburn for more than three months.
- Heartburn with lightheadedness, sweating or dizziness.
- Chest pain or shoulder pain with lightheadedness, shortness of breath, sweating, or pain spreading to the arms, neck, or shoulders.
- Frequent chest pain
- Frequent wheezing related to heartburn
- Stomach pain, nausea or vomiting and unexplained weight loss.

Stop use and ask a doctor if:

- Your condition does not improve or worsens after 14 days of treatment.
- You need to take the course of treatment more frequently than every 4 months.

AVAILABILITY

Omeprazole (Omepron®) 20 mg capsule in box of 30s (in blister foil)

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

Manufactured by STANDARD CHEM. & PHARM.CO., LTD.
No. 6-20 Tu-Ku Li, Hsin-Ying (730) Tainan, Taiwan, Republic of China
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