

# PROMESEC

## Gastro-Resistant Capsules

### Omeprazole 20mg

#### Description

Reddish brown cap / Pink body size '2' hard gelatin capsule imprinted with 'H'on cap and 'O2' on body, filled with white to off white pellets.

#### Ingredients

Each capsule contains 20 mg Omeprazole (Form B).

Other ingredients include Hypromellose, Purified Water, Sodium Hydroxide, Talc, Macrogol, Methacrylic Acid Ethyl Acrylate, Titanium Dioxide, Gelatin, Iron Oxide Red, Black Iron Oxide, Butyl Alcohol, Dehydrated Alcohol, Isopropyl Alcohol, Potassium Hydroxide, Propylene Glycol, Shellac, Strong Ammonia Solution, Starch (of maize), and Sucrose.

#### What is this medicine used for

Promesec is used for the relief of heartburn symptoms associated with stomach acid reflux. It belongs to a group of medicines called 'proton pump inhibitors' (PPI) and works by reducing the amount of acid produced in your stomach.

#### How to take this medicine

Adults 18 years old and above:

One capsule to be taken once daily for up to 14 days. Best taken 30 minutes before a meal.

Capsules should be swallowed whole with liquid. Do not crush or chew the capsule.

#### When should you not take this medicine

Medical advice should be sought before use if you experience any of the following: heartburn for over 3 months; chest pain or shoulder pain with shortness of breath; sweating, pain spreading to arms, neck of shoulders or light-headedness; frequent wheezing, particularly with heartburn; unexplained weight loss; nausea or vomiting; stomach pain; pain when swallowing food; vomiting with blood; bloody or black tarry stools.

This medicine should be avoided if you have a known history of hypersensitivity (allergy) to omeprazole. Omeprazole must not be taken together with Nelfinavir (a medication for HIV).

Inform your doctor or pharmacist if you have liver disease or are pregnant/breast-feeding.

#### Interactions with other medications

Inform your doctor and/or pharmacist if you are taking, have recently taken or plan to take other medications, nutritional supplements or herbal products.

Be sure to mention any of the following: Antibiotics (e.g. Rifampicin); Blood-thinning medication (e.g. Warfarin, clopidogrel); Oral antifungal or anti-yeast medication (e.g. Itraconazole, Ketoconazole); Anti-anxiety medication (e.g. Diazepam); Complementary medicines (e.g. St John's Wort); Heart medication (e.g. Digoxin); Immune system medication (e.g. Tacrolimus, Cyclosporine, Methotrexate); Anti-viral medication for HIV (e.g. Atazanavir, Nelfinavir), and Anti-epilepsy medication (e.g. Phenytoin).

#### Side effects

The common side effects are:

- Headache
- Stomach pain, diarrhoea, constipation
- Nausea and/or vomiting
- Cough
- Dizziness
- Back pain

Rarely, low magnesium level (hypomagnesemia) may occur. Most cases occur after using PPIs for 3-12 months.

Promesec can cause serious side effects including:

Certain types of lupus erythematosus. Lupus erythematosus is an autoimmune disorder (the body's immune cells attack other cells or organs in the body). Some people who take PPI medicines, may develop certain types of lupus erythematosus or have worsening of the lupus they already have. Call your doctor right away if you have any new or worsening pain or rash on your cheeks or arms that gets worse in the sun.

Dizziness and visual disturbances may occur. If affected, please do not drive or operate machines.

#### Precautions

Inform your doctor and/or pharmacist immediately if you experience any allergic symptoms or symptoms of serious side effects such as:

- Swelling of eyes and lips
- Rashes which resembles mosquito bites
- Rashes which are blistering, or peeling
- Difficulty in breathing
- Fever, chills, sore throat and muscle ache
- Sudden and severe stomach pain, diarrhea, nausea, or vomiting
- Unusual bleeding, bruising, or weakness
- Yellowing of the skin or whites of the eyes
- Dark brown or red urine

#### Missed dose

If you miss a dose, take it as soon as remembered; do not take it if it is near the time for the next dose, instead, skip the missed dose and resume your usual dosing schedule. Do not "double-up" the dose to catch up.

#### Signs and symptoms of overdose

Symptoms of overdose may include drowsiness, headache and increased heartbeat.

#### Steps to take when taken more than the recommended dosage

If overdose is suspected, contact your local poison center or emergency room. There is no specific antidote for overdose. Treatment should be symptomatic and supportive.

#### When to consult your doctor

If heartburn continues or worsens.  
If more than one course of treatment is taken every 4 months.

#### How should you keep this medicine

Keep out of reach and sight from children.  
Keep this medicine in its original container until use.  
Store below 30°C in a cool dry place.  
Avoid direct exposure to sunlight.

Product Registration Holder

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