

Promesec Capsule 20mg

Omeprazole 20mg

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What Promesec Capsule 20mg is used for

Promesec Capsule 20mg is used to treat the following conditions:

- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Promesec Capsule 20mg can also be used to stop ulcers from forming if you are taking NSAIDs.
- Ulcers infected with bacteria called '*Helicobacter pylori*'.
- 'Gastro-esophageal reflux disease' (GERD). This is where acid from the stomach escapes into the oesophagus (the tube which connects your throat to your stomach), causing pain, inflammation and heartburn.
- Reflux oesophagitis (inflammation of the lining of oesophagus)
- Too much acid in the stomach as a result of growth in the pancreas or upper part of the intestine (Zollinger-Ellison Syndrome).
- Acid related dyspepsia (indigestion).

How Promesec Capsule 20mg works

Promesec Capsule 20mg contains the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid produced in your stomach.

Ask your doctor if you have any questions about why this medicine has been prescribed to you. Your doctor may have prescribed it for another reason.

Before you use Promesec Capsule 20mg

- When you must not take it

Do not take Promesec Capsule 20mg

- If you are allergic (hypersensitive) to omeprazole or any of the ingredients of Promesec Capsule 20mg.
- If you are allergic to medicines containing other proton pump inhibitors like pantoprazole or lansoprazole.
- If you are taking a medicine containing nelfinavir (used for HIV infection).
- If you are lactose intolerance (experience stomach discomfort after taking any milk products).

If you are not sure, talk to your doctor or pharmacist before taking Promesec Capsule 20mg.

- Before you start to take it

Promesec Capsule 20mg may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Promesec Capsule 20mg or while you are taking it, talk to your doctor straight away:

- You lose a lot of weight for no reason.
- You have problems with

swallowing.

- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).
- You having diarrhea that does not improve.
- You having lesion at sun exposed skin.

If you take Promesec Capsule 20mg on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

If you are taking Promesec Capsule 20mg for at least 3 months, you might have risk in having severe hypomagnesaemia. Your doctor will consider to measure your magnesium level before treatment if you are taking drugs that might cause hypomagnesaemia.

Taking a proton pump inhibitor like Promesec Capsule 20mg, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine, it might also lead to malabsorption of vitamin B12.

Tell your doctor if you have osteoporosis.

Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A)

Tell your doctor if you have hereditary problems of galactose intolerance.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines and Promesec

Capsule 20mg may interfere with each other.

Do not take Promesec Capsule 20mg if you are taking a medicine containing nelfinavir (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole, Itraconazole, Voriconazole or Posaconazole (used to treat infections caused by a fungus)
- Erlotinib (used to treat cancer)
- Clopidogrel (used to prevent blood clots (thrombi))
- Digoxin (used to treat heart problems)
- Warfarin or other vitamin K blockers (used to thin your blood)
- Atazanavir, Saquinavir or Ritonavir (used to treat HIV infection)
- Methotrexate (used to treat cancer)
- Cilostazol (used to treat intermittent claudication (cramping pain in the leg caused by obstruction of the blood vessels))
- Clarithromycin (used to treat infection caused by bacteria)
- Rifampicin (used to treat tuberculosis (lung infection))
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Phenytoin (used in epilepsy). Your doctor will need to monitor you when you start or stop taking Promesec Capsule 20mg.
- Tacrolimus (in cases of organ transplantation) Your doctor will need to monitor you when you start or stop taking Promesec Capsule 20mg.

How to use Promesec Capsule 20mg

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this

leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

- How much to use

To treat symptoms of GERD and acid related dyspepsia (indigestion):

- The usual dose is 10mg to 20mg once a day for 4 weeks.
- Talk to your doctor if symptom control is not achieved after 4 weeks of treatment with Promesec Capsule 20mg.
- To treat reflux oesophagitis:
 - The usual dose is 20mg once a day for 4 weeks. You may need to continue taking the same dose for another 4 weeks if your ulcer is not fully healed after the initial course.
 - For serious reflux oesophagitis, dose of 40 mg once daily for 8 weeks is recommended.
 - For long term management of healed reflux oesophagitis, dose of 10mg once a day is recommended.

To treat duodenal ulcer:

- The usual dose is 20 mg once a day for 2 weeks. You may need to continue taking the same dose for another 2 weeks if your ulcer is not fully healed after the initial course.
- For slow healing duodenal ulcer, dose of 40 mg once a day for 4 weeks is recommended.

To treat gastric ulcer:

- The usual dose is 20 mg once a day for 4 weeks. You may need to continue taking the same dose for another 4 weeks if your ulcer is not fully healed after the initial course.
- For slow healing gastric ulcer, a dose of 40 mg once a day for 8 weeks is recommended.

To prevent the duodenal and stomach ulcers from coming back:

- The usual dose is 10 mg or 20

mg once a day. Your doctor may increase the dose to 40 mg once a day.

To treat duodenal and gastric ulcers caused by NSAIDs:

- The usual dose is 20 mg once a day for 4 weeks. You may need to continue taking the same dose for another 4 weeks if your ulcer is not fully healed after the initial course.

To prevent duodenal and gastric ulcers caused by NSAIDs:

- The recommended dose is 20mg once daily.
- To treat Zollinger-Ellison Syndrome:

- The recommended dose is 60mg once daily. Your doctor may adjust the dose according to your condition.

- To treat ulcers infected with bacteria '*Helicobacter pylori*' using triple therapy regimens:

- Omeprazole 20mg, amoxicillin 1g and clarithromycin 500mg, all twice a day for one week or

- Omeprazole 20mg, metronidazole 400mg (or tinidazole 500mg) and clarithromycin 250mg, all twice a day for one week, or

- Omeprazole 40mg once daily with amoxicillin 500mg and metronidazole 400mg both three times a day for one week.

To treat ulcers infected with bacteria '*Helicobacter pylori*' using dual therapy regimens:

- Omeprazole 40 to 80mg daily with amoxicillin 1.5g daily in divided doses for two weeks.

- Omeprazole 40mg once daily and clarithromycin 500mg three times a day for two weeks.

- When to use it

You can swallow the whole capsule with half glass of water in the morning, preferably with empty stomach.

If you have difficulties in swallowing the capsule, you can open the capsule and swallow the contents with half glass of water.

You can also mix the contents in fruit juice or non-carbonated water, stir well and drink it immediately (or within 30 minutes) with half glass of water.

- How long to use it

Continue taking your medicine for as long as your doctor tells you.

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your capsule as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

- If you use too much (overdose)

If you think you have been given too much Promesec Capsule 20mg, talk to your doctor straight away.

You might experience nausea, vomiting, abdominal pain and headache. Symptomatic treatment can be given if needed.

While you are using it

- Things you must do

Always follow your doctor's instructions carefully.

Tell your doctors, dentists and pharmacists who are treating you that you are taking Promesec Capsule 20mg.

If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking Promesec Capsule 20mg.

Before taking Promesec Capsule 20mg, tell your doctor if you are

pregnant or trying to get pregnant. Your doctor will decide whether you can take Promesec Capsule 20mg during this time.

- Things you must not do

Do not take Promesec Capsule 20mg to treat any unrelated complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how Promesec Capsule 20mg affects you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possibly with pain in the joints. (Subacute Cutaneous Lupus Erythematosus, SCLE)
- Fever, extreme tiredness, pus/blood in urine.
- Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate
- Fracture in the hip, wrist or spine
- Watery stool, stomach pain and fever that do not go away.
- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerver problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems

(depression, memory loss or behavioral changes).

- a) Subacute Cutaneous Lupus Erythematosus (SCLE)
Frequency "not known"
- b) Interstitial Nephritis
Kidney problems (interstitial nephritis)
- c) Hypomagnesaemia
Frequency "not known":
Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.
- d) Fracture
Frequency "uncommon": Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis)
- e) Clostridium Difficile Diarrhea
Severe diarrhea which may be caused by an infection (Clostridium difficile) in your intestines.
- f) Fundic Gland Polyps (Benign)
Frequency "Common": Benign polyps in the stomach.
- g) Vitamin B12 Deficiency
Proton pump inhibitors may cause vitamin B12 deficiency.

Ask your doctor or pharmacist to answer any questions you may have.

Common side effects:

- Headache
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence)
- Feeling nausea or vomiting

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Promesec Capsule 20mg

- Storage

Keep your medicine in the original container. If you take it out of its original container it may not be kept in its best condition.

Keep your medicine in a dry place where the temperature stays below 30°C. Protect from light.

Do not store Promesec Capsule 20mg or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it out of reach of children.

A locked cupboard at least one- and-a-half metres above the ground is a good place to store the medicines.

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with the remaining medicine.

Product Description

- What it looks like

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

Active ingredient:

- Omeprazole

Inactive ingredients:

- Sugar
- Hypromellose
- Talc
- Sodium hydroxide
- Methacrylic acid ethyl acrylate
- Macrogol
- Titanium dioxide

- MAL number

MAL18056152AZ

Manufacturer

Hetero Labs Limited,
Unit III, 22-110, I.D.A.,
Jeedimetla, Hydrerabad –
500055, Telangana, India.

Product Registration Holder

Duopharma Marketing Sdn. Bhd.
Lot 2, 4, 6, 8 & 10, Jalan P/7,
Section 13, Bangi Industrial
Estate, 43650, Bandar Baru
Bangi, Selangor Darul Ehsan,
Malaysia.

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