

OMEPRAZOLE PIL

1. What this product is and what it is used for

Each Gastrocap™ (gastro - resistant capsule) contains 10 mg, 20 mg or 40 mg of omeprazole, respectively.

It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces. Gasec™ is used to treat the following conditions:

In adults:

- 'Gastro-esophageal reflux disease' (GERD). This is the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Ulcers which are infected with bacteria called 'Helicobacter pylori'. Your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Gasec™ can also be used to stop ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

In children: Children over 1 year of age and $\geq 10\text{ Kg}$

- 'Gastro-esophageal reflux disease' (GERD). This is the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn. In children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

Children and adolescents over 4 years of age • Ulcers which are infected with bacteria called 'Helicobacter pylori'. If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

2. What you need to know before you use this product

Do not take Gasec™ • if you are allergic (hypersensitive) to omeprazole or any of the other ingredients of Gasec™.

- 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 (for HIV infection).

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

Take special care with Gasec™

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

- 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 are due to have a specific blood test (Chromogranin A).

If you take Gasec™ 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.

Taking a proton pump inhibitor like Gasec™, 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).

Subacute cutaneous lupus erythematosus (SCLE): Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping this medication. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.

This medicine contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose - galactose malabsorption or sucrase - isomaltase insufficiency should not take this medicine. 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. This is because Gasec™ can affect the way some medicines work and some medicines can have an effect on Gasec™.

Do not take Gasec™ 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, posaconazole or voriconazole (used to treat infections caused by a fungus). • Digoxin (used to treat heart problems) • Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Gasec™ • Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Gasec™. • Rifampicin (used to treat tuberculosis) • Atazanavir (used to treat HIV infections)
- Tacrolimus (in cases of organ transplantation) • St John's Hypericum wort perforatum() (used to treat mild depression) • Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to prevent blood clots (thrombi)) • Erlotinib (used to treat cancer).
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) –if you are taking a high dose of methotrexate, your doctor may temporarily stop your Gasec™ treatment.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Gasec™ to treat ulcers caused by Helicobacter pylori infection, it is very important that you tell your doctor about any other medicines you are taking.

Pregnancy and breast-feeding

Before taking Gasec™, tell your doctor if you are pregnant or trying to get pregnant. Your doctor will decide whether you can take Gasec™ during this time.

Your doctor will decide whether you can take Gasec™ if you are breastfeeding.

Driving and using machines

Gasec™ is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

3. How to use this product.

Always take Gasec™ exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition and how old you are.

The usual doses are given below.

Adults:

To treat symptoms of GERD such as heartburn and acid regurgitation:

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is 20 mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 8 weeks if your gullet has not yet healed.
 - The usual dose once the gullet has healed is 10 mg once a day.
 - If your gullet has not been damaged, the usual dose is 10 mg once a day.

To treat ulcers in the upper part of the intestine (duodenal ulcer):

- The usual dose is 20 mg once a day for 2 weeks. Your doctor may tell you to take the same dose for a further 2 weeks if your ulcer has not yet healed. • If the ulcer do not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

To treat ulcers in the stomach (gastric ulcer):

- The usual dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your ulcer has not yet healed. • If the

ulcer do not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

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 stomach ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- The usual dose is 20 mg once a day for 4 to 8 weeks.

To prevent duodenal and stomach ulcers if you are taking NSAIDs:

- The usual dose is 20 mg once a day.

To treat ulcers caused by Helicobacter pylori infection and to stop them coming back:

- The usual dose is 20 mg Gasec™ twice a day for one week.

- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole.

To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):

- The usual dose is 60 mg daily.

- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for.

Children:

To treat symptoms of GERD such as heartburn and acid regurgitation:

- Children over 1 year of age and with a body weight of more than 10 kg may take Gasec™.

The

dose for children is based on the child's weight doctor will decide the correct dose.

To treat ulcers caused by Helicobacter pylori infection and to stop them coming back:

- Children aged over 4 years may take Gasec™. The dose for c weight and the doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

Taking this medicine

- It is recommended that you take your capsules in the morning.
- You can take your capsules with food or on an empty stomach.

- Swallow your capsules whole with half a glass of water. Do not chew or crush the capsules.

If you take more Gasec™ than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Gasec™ If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Gasec™ can cause side effects, although not everybody gets them.

If you notice any of the following rare but serious side effects, stop taking Gasec™ and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose-Johnson and syndrome'genitals. epidermal necrolysis'.

- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

The frequency of adverse events listed below is defined using the following convention:

very common (> 1/10); common (> 1/100 and < 1/10); uncommon (> 1/1,000 and < 1/100); rare (> 1/10,000 and < 1/1,000); very rare (< 1/10,000), not known (cannot be estimated from the available data).

Other side effects include:

- Common side effects • Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).

Uncommon side effects

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as "pins and needles".
- Spinning feeling (vertigo).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.

Rare side effects • Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely. • Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing. • Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps. • Feeling agitated, confused or depressed.

- Taste changes. • Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm). • Dry mouth. • An inflammation of the inside of the mouth. • An infection called "thrush" caused by a fungus which can affect • Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness. • Hair loss (alopecia).
- Skin rash on exposure to sunshine. • Joint pains (arthralgia) or muscle pains (myalgia). • Severe kidney problems (interstitial nephritis).
- Increased sweating.

Very rare side effects • Changes in blood count including agranulocytosis (lack of white blood cells) • Aggression. • Seeing, feeling or hearing things that are not there (hallucinations). • Severe liver problems leading to liver failure and inflammation of the brain.

- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens Johnson syndrome, toxic epidermal necrolysis) • Muscle weakness. • Enlarged breasts in men.

Not known • Inflammation in the gut (leading to diarrhoea).

- If you are on Gasec™ for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Gasec™ 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.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store this product

Keep out of the reach and sight of children.

Do not store above 30° C. Keep the bottle tightly closed in order to protect from moisture. Use within 4 weeks after opening.

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

6. Further information

a. What this product contains

- The active substance is omeprazole. Each Gastrocaps™ (gastro resistant capsule) contains 10 mg, 20 mg or 40 mg of omeprazole. - The other ingredients are; - Gastro - resistant pellets: Sugar sphere, hydroxypropyl methylcellulose, disodium hydrogen phosphate, Syloid 244, titanium dioxide (E 171), Eudragit L30 D, Citroflex 2, talc. - Capsule composition: Gelatine, titanium dioxide (E 171), iron oxide (E 172), indigotine (E 132).

b. What this product looks like and contents of the pack

White bottle of high density polyethylene (HDPE) with cap and desiccant. Gasec - 10: Packs of 14 and 28 Gastrocaps. Gasec - 20: Packs of 7, 14, 28 and 56

Gastrocaps. Gasec - 40: Packs of 14 and 28 Gastrocaps. Not all pack sizes may be marketed.

c. Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

Acino AG, Miesbach, Germany

Manufacturer

Manufactured by Acino Pharma AG, Aesch, Switzerland. Secondary Packaged by Batterjee Pharma, Jeddah, Saudi Arabia

d. This leaflet was last revised in {MM/YYYY}

- This leaflet was last revised in September 2017.