

PATIENT INFORMATION LEAFLET
(OMLINK 20) OMEPRAZOLE DELAYED-RELEASE CAPSULES USP 20 MG
[Omeprazole USP]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. What omeprazole capsules is and what it is used for
2. Before you use omeprazole capsules
3. How to use omeprazole capsules
4. Possible side effects
5. How to store omeprazole capsules
6. Further information

1. WHAT OMEPRAZOLE CAPSULES IS AND WHAT IT IS USED FOR

It contain active ingredient omeprazole is a proton pump inhibitor it reduces gastric acid secretion through a highly selective mechanism of action. It produces specific dose dependent inhibition of the enzyme H⁺-K⁺-ATPase (the 'proton pump') in the parietal cell. As this action inhibits the final stage of gastric acid formation, there is an effective inhibition of both basal and stimulated acid secretion irrespective of the stimulus to acid formation. It is used in the treatment of duodenal ulcer, gastric ulcer, reflux oesophagi tis (gastro-oesophageal reflux) and Zollinger-Ellison syndrome. It is also used in prevention of stress ulcers, acid aspiration syndrome during anaesthesia and treatment of upper gastrointestinal bleeding.

2. BEFORE YOU USE OMEPRAZOLE CAPSULES

Do not use it if you are allergic to omeprazole or any of the other ingredients of this medicine. It is contraindicated in children safety and effectiveness of omeprazole in children have not been established. It is not recommended for use in children since no adequate data are available. Do not take if any of the above apply to you. If you are not sure, talk to your physician, pharmacist or nurse before having omeprazole capsules .

Take special care with omeprazole capsules: Talk to your physician before taking omeprazole capsules. **Warnings and Precautions:** Maintenance therapy: It should not be used as maintenance therapy for treatment of patients with duodenal ulcer disease. Duration of therapy (GERD): The efficacy of Omeprazole used for > 8 weeks has not been established. In the rare patient not responding to 8 weeks of treatment, an additional 4 weeks of treatment may help. If there is recurrence of erosive or symptomatic GERD poorly responsive to customary medical treatment, an additional 4 to 8 week course of Omeprazole may be considered. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with Omeprazole.

Elderly: Bioavailability may be increased. **Children:** Safety and efficacy in children have not been established.

Using other medicines: Concurrent use with prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolised by oxidation in the liver. Monitoring of patients also receiving warfarin or phenytoin is recommended and a reduction of dose of warfarin and phenytoin may be necessary. However, concomitant treatment with omeprazole 20 mg daily did not change the blood concentration of phenytoin in patients on continuous treatment with phenytoin. No interaction with propranolol, theophylline, metoprolol, lidocaine or quinidine has been found, but interactions with other drugs also metabolised via the cytochrome P-450 enzyme system cannot be excluded. No interactions with concomitantly administered antacids have been found.

Using omeprazole capsules with food and drink: Patients can take this medicine with or without food. Swallow capsules whole, do not bite, chew or divide.

Pregnancy and breast-feeding: Before taking any medicine for advice consult to direction of physician. **Pregnancy:** There are no adequate or well controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the risk to the foetus. **Use in breast-feeding:** It is not known whether omeprazole is excreted in breast milk therefore, it should not be used during breastfeeding infants.

Driving and using machines: There are possible side effects associated omeprazole 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. If affected, you should not drive or operate machinery.

It contains: each hard gelatin capsule contains: omeprazole USP 20 mg (as enteric coated granules) excipients q.s. approved colours used in empty capsule shell.

3. HOW TO USE OMEPRAZOLE CAPSULES

Always take your dose of omeprazole capsules exactly as direction by physician or a nurse or health care provider or pharmacist has told you, if you are not sure. Do not change your usual dose without talking to your physician.

How omeprazole capsules will be given to you: Method of administration: For Oral Use Only. Patients can take this medicine with or without food. Swallow capsules whole, do not bite, chew or divide. **The usual recommended doses:** The recommended dosage is 20 mg Omeprazole once daily. **Duodenal Ulcer, Gastric Ulcer and Reflux Oesophagitis :** take 20 mg Omeprazole once daily. In patients with duodenal ulcer symptoms, relief is rapid and healing occurs within 2 weeks in most cases. For those patients who may not have fully healed after the initial course, healing usually occurs during a further 2-week treatment period.

In patients with gastric ulcer or reflux oesophagi tis symptom, relief is rapid and healing occurs within 4 weeks in most cases.

For those patients who may not have fully healed after the initial course, healing usually occurs during a further 4-week treatment period. In patients refractory to other treatment regimens, 40 mg Omeprazole once daily has been used and healing achieved, usually within 4 weeks in patients with duodenal ulcer and within 8 weeks in patients with gastric ulcer or reflux oesophagi tis.

Zollinger-Eilison Syndrome: The recommended initial dosage is 60 mg Omeprazole once daily. The dosage should be adjusted individually and treatment continued as long as it is clinically indicated. All patients with severe disease and inadequate response to other therapies have been effectively controlled and > 90% of the patients maintained on doses of 20-120 mg daily. With doses >80 mg daily, the dose should be divided and given twice daily.

For Elderly Patients: No dose adjustment is necessary in the elderly.

Use in children: It is not recommended for use in children. There is no experience with in children.

If you more omeprazole capsules than you should: the over dosage is unlikely to oral route. By accident, anyone take this medicine, experience with omeprazole over dosage. There is no information available on the effects of over dosage in man and specific recommendations for treatment cannot be given. Single oral doses of up to 160 mg have been well tolerated.

If you forget to omeprazole capsules: It is important to take omeprazole capsules as prescribed by your physician. Take your normal dose immediately and continue taking your capsules at the usual time of day, do not take a double dose to make up for the missed dose. If you have any further questions on the use of this product, ask your physician, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Like all medicines, it can cause side effects, although not everybody gets them. Following adverse effects have been reported with oral administration of omeprazole: Headache, diarrhoea, constipation, abdominal pain, nausea/vomiting and flatulence have been reported at a frequency > 1% by patients treated with omeprazole in clinical trials. Furthermore, the following events have been reported from marketed use of omeprazole capsule: Rarely: Rash, urticaria and/or pruritus, dizziness, paraesthesia, somnolence, insomnia, vertigo and malaise. In Isolated Cases: Arthralgia, muscular weakness, myalgia, reversible mental confusion, agitation, depression and hallucination (predominantly in severely ill patients), stomatitis and gastrointestinal candidiasis, increased liver enzymes with or without increased bilirubin values, gynecomastia, leukopenia, thrombocytopenia, peripheral oedema, blurred vision and taste perversion. Irreversible visual impairment has been reported in isolated cases of critically ill patients who have received omeprazole IV injection, especially at high doses, but no causal relationship has been established.

5. HOW TO STORE OMEPRAZOLE CAPSULES

Keep this medicine out of the sight and reach of children. Store below 25°C. Protect from light & moisture. Light. Do not use this medicine after the expiry date which is stated on the carton. 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. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as omeprazole USP (As enteric coated granules) Excipients: Approved colours used in empty capsule shell. Size: Pink/white color size "2" capsule containing white to off-white coloured round enteric coated pellets. 10 Capsules are packed in Alu-strip pack. 10 Alu-strip packed in printed carton along with packaging insert.

Manufactured by:

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Phone: +91-079-41078096,

Telefax: +91-79-41078062

Email: hiren@lincolnpharma.com

Website: www.lincolnpharma.com

For any information about this medicinal product, please contact the local representative of the supplier:

Lincoln Pharmaceuticals Limited Trimul Estate, Khatraj, Taluka: Kalol, District: Gandhinagar Gujarat, India. Phone: +91-079-41078096 Telefax: +91-79-41078062 Email: hiren@lincolnpharma.com Website: www.lincolnpharma.com	Abacus Pharma (A) Ltd Kigali city market, B1-R85, PO Box 4344, Kigali, Rwanda. Phone: +91-079-41078096 Telefax: +91-79-41078062 Email: abacuspharmacist@gmail.com
--	---

Date of publication or revision

03.02.2023