VOCINTI Abbreviated Product Information

Full prescribing information available upon request

Please refer to full package insert before prescribing (27 Oct 2021/ CCDS v3 & v3.1)

Composition: Each tablet contains 10mg and 20mg of Vonoprazan. **Indication:** Treatment of gastric ulcer (GU), Treatment of duodenal ulcer (DU), Treatment of reflux esophagitis (RE) (erosive esophagitis EE), Maintenance treatment of reflux esophagitis (erosive esophagitis) in patients with repeat recurrence and relapse of the condition. The duration of administration in the long-term efficacy clinical Study OCT-001 is up to 52 weeks. Prevention of recurrence of gastric ulcer or duodenal ulcer during NSAIDs administration. Adjunct to Helicobacter pylori eradication associated with: Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, the stomach after endoscopic resection of early stage cancer, or Helicobacter pylori gastritis. **Dosage: Duodenal ulcer** 20 mg daily limited to 6 weeks **Gastric ulcer** 20 mg daily limited to 8 weeks **Treatment of Reflux esophagitis (RE) (Erosive esophagitis (EE))** 20 mg daily for 4 to 8 weeks **Maintenance of healing of RE** 10 mg daily (may increase to 20 mg daily up to 52 weeks) **Prevention of recurrence of gastric ulcer or duodenal ulcer during NSAIDs administration** 10 mg daily **Adjunct to *H. pylori* eradication** 20 mg twice daily for 7 days with combination of 2 antibiotics, following local label recommendations. **Contraindications:** Hypersensitivity to the active ingredients or to any of the excipients. **Special precautions:** Hepatotoxicity, elevation of intragastric pH, renal impairment, hepatic impairment, pregnancy and lactation, masking of symptoms associated with gastric malignancy, Clostridium difficile associated diarrhoea including pseudomembranous colitis and bone fracture, geriatric use, renal impairment, hepatic impairment, Vonoprazan has not been studied in patients under 18 years of age. **Undesirable Effects:** Constipation, diarrhoea. **Drug-Drug Interactions:** Administration of vonoprazan results in elevation of intragastric pH, suggesting that it may interfere with the absorption of drugs where gastric pH is an important determinant of oral bioavailability. Use of vonoprazan is therefore not recommended with some of these drugs for which absorption is dependent on acidic intragastric pH such as atazanavir and nelfinavir, due to significant reduction in their bioavailability. Co-administration of midazolam (a sensitive CYP3A4 substrate) with multiple doses of vonoprazan increased concentration of midazolam by 1.9-fold in healthy subjects. Caution is advised when vonoprazan is co-administered with other sensitive CYP3A4 substrates, notably those having a narrow therapeutic index. **Storage conditions:** Store below 30°C. **Shelf-life:** 3 years. **Packs:** Pack of 10 Tablets (Sample) or 30 Tablets. **Name and Address of Product Registration Holder:** Takeda Malaysia Sdn Bhd, Unit TB-L13-1, Level 13, Tower B, Plaza 33, No.1 Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor, Malaysia.

Refer to full prescribing information for further details & is available upon request.

Suspected Adverse events should be reported to Takeda at: AE.VMAPS@takeda.com

Date of Preparation of the API: May 2022

Document number: pi-01058