

VONOTOR

To be sold by retail on the prescription of a Registered Medical Practitioner only

Abbreviated Prescribing information for **VONOTOR** [Vonoprazan Tablets 10 mg / 20mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Vonoprazan is a potassium competitive acid blocker (PCAB). Which suppresses both basal and stimulated gastric acid secretion at the secretory surface of the gastric parietal cell through inhibition of the H⁺, K⁺-ATPase enzyme system in a potassium-competitive manner. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, vonoprazan has been characterized as a type of gastric proton-pump inhibitor, in that it blocks the final step of acid production.

INDICATION: It Is Indicated for the treatment of reflux esophagitis (RE).

- Treatment of gastric ulcer (GU).
- Treatment of duodenal ulcer (DU).
- Prevention of recurrence of gastric ulcer or duodenal ulcer during low-dose aspirin administration.
- 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 AND ADMINISTRATION: Film Coated Vonoprazan Tablets 10 mg / 20 mg
Vonoprazan can be taken without regard to food or timing of food.

CONTRAINDICATION: Vonoprazan is contraindicated in patients with a known hypersensitivity to vonoprazan or any component of it. Reactions have included anaphylactic shock. It is contraindicated with rilpivirine-containing products.

WARNINGS & PRECAUTIONS: Acute tubulointerstitial nephritis (TIN) has been reported with Vonoprazan. If suspected, discontinue Vonoprazan and evaluate patients with suspected acute TIN. Several published observational studies suggest that PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine. Long-term use of acid-suppressing drugs can lead to malabsorption of Vitamin B12 caused by hypo- or achlorhydria. Vitamin B12 deficiency has been reported post marketing with vonoprazan.

DRUG INTERACTIONS: Concomitant administration of clarithromycin with other drugs can lead to serious adverse reactions, including potentially fatal arrhythmias, and are contraindicated. Amoxicillin also has drug interactions. Vonoprazan is a CYP2C19 inhibitor. Vonoprazan may reduce plasma concentrations of the active metabolite of clopidogrel and may cause reduction in platelet inhibition. Vonoprazan may increase exposure of CYP2C19 substrate drugs (e.g., citalopram, cilostazol).

ADVERSE REACTIONS: Acute Tubulointerstitial Nephritis, Clostridioides difficile-Associated Diarrhoea, Bone Fracture, Severe Cutaneous Adverse Reactions, Vitamin B12 (Cobalamin) Deficiency, Hypomagnesemia and Mineral Metabolism, Fundic Gland Polyps, Gastritis, Diarrhea, Abdominal distension, Abdominal pain, Nausea, Dysgeusia, Vulvovaginal Candidiasis, Headache, Hypertension, Nasopharyngitis.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/VONOTOR 10 mg & 20 mg/APR 2025/01/ABPI

(Additional information is available on request)