

## VELOZ INJECTION (LYOPHILIZED)

Abbreviated Prescribing information for VELOZ INJECTION (LYOPHILIZED)  
[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** Rabeprazole belongs to a class of antisecretory compounds (substituted benzimidazole proton- pump inhibitors) that do not exhibit anticholinergic or histamine H<sub>2</sub>-receptor antagonist properties, but suppress gastric acid secretion by inhibiting the gastric H<sup>+</sup>, K<sup>+</sup>ATPase at the secretory surface of the gastric parietal cell. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, rabeprazole has been characterized as a gastric proton-pump inhibitor. Rabeprazole blocks the final step of gastric acid secretion. In gastric parietal cells, rabeprazole is protonated, accumulates, and is transformed to an active sulfenamide. When studied in vitro, rabeprazole is chemically activated at pH 1.2 with a half-life of 78 seconds. It inhibits acid transport in porcine gastric vesicles with a half-life of 90 seconds.

**INDICATIONS:** For the short-term treatment of gastric and duodenal ulcer, Gastroesophageal reflux Disease (GERD) as an alternative to oral therapy in patients who are unable to take oral proton pump inhibitors.

**DOSAGE AND ADMINISTRATION:** As directed by the physician.

**CONTRAINDICATION:** Rabeprazole is contraindicated in patients with known hypersensitivity to rabeprazole, or to any component of the formulation. RABEPRAZOLE is contra-indicated in pregnancy and during breast-feeding. rabeprazole and warfarin have not been adequately evaluated in patients. There have been reports of increased INR and prothrombin time in patients receiving a proton pump inhibitor and warfarin concomitantly. Acute Interstitial Nephritis, Cyanocobalamin (vitamin B-12) Deficiency, Clostridium difficile Associated Diarrhea, Bone Fracture, Hypomagnesemia. concomitant use of PPIs with methotrexate (primarily at high dose) may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to established treatment.

**WARNINGS & PRECAUTIONS:** Take special care in presence of gastric malignancy, acute interstitial nephritis, concomitant use with Warfarin, Cyanocobalamin (Vitamin B-12) deficiency, Clostridium Difficile associated diarrhea, bone fracture, hypomagnesemia and concomitant use of Rabeprazole with methotrexate. You are allergic to other proton pump inhibitor medicines or 'substituted benzimidazoles. Blood and liver problems have been seen in some patients but often get better when VELOZ inj is stopped. You have a stomach tumour. You have ever had liver problems. If you are taking atazanavir- for HIV infection. If you have reduced body stores or risk factors for reduced vitamin B12 and receive long term treatment with rabeprazole sodium. As with all acid reducing agents, rabeprazole sodium may lead to a reduced absorption of vitamin B12. If you have ever had a skin reaction after treatment with a medicine similar to VELOZ inj that reduces stomach acid If you get

a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with VELOZ inj. Remember to also mention any other ill-effects like pain in your joints. VELOZ inj should not be used in children. Do not use VELOZ inj if you are pregnant or if you are breast-feeding

**DRUGS INTERACTIONS:** Rabeprazole is metabolized by the cytochrome P450 (CYP450) drug metabolizing enzyme system. Studies in healthy subjects have shown that rabeprazole does not have clinically significant interactions with other drugs metabolized by the CYP450 system, such as warfarin and theophylline given as single oral doses, diazepam as a single intravenous dose, and phenytoin given as a single intravenous dose (with supplemental oral dosing). Steady state interactions of rabeprazole and other drugs metabolized by this enzyme system have not been studied in patients. rabeprazole, with warfarin increased INR and prothrombin time in patients rabeprazole inhibited cyclosporine metabolism with an IC50 of 62 micromolar. rabeprazole, amoxicillin, and clarithromycin resulted in increases in plasma concentrations of rabeprazole and 14-hydroxyclearithromycin.

**ADVERSE REACTIONS:** Infections, Neutropenia Leucopenia, Thrombocytopenia, Hypersensitivity Anorexia, Depression Insomnia, Nervousness, Depression, , Headache or feeling dizziness, Visual disturbance, Peripheral oedema, Cough Pharyngitis Rhinitis, Bronchitis Sinusitis, Diarrhoea Vomiting Nausea Abdominal pain Constipation Flatulence Fundic gland, Dyspepsia Dry mouth Eructation, Gastritis Stomatitis, Taste disturbance, Microscopic colitis, Hepatitis Jaundice Hepatic encephalopathy, Rash Erythema, Pruritus Sweating Bullous reactions, Erythema multiforme, toxic epidermal necrolysis , Subacute cutaneous lupus erythematosus, Non- specific pain Back pain, Myalgia Leg cramps Arthralgia Fracture of the hip, wrist or spine, Urinary tract infection, Interstitial nephritis, Acute kidney injury, Gynecomastia, Chest pain Chills Pyrexia, Asthenia Influenza like illness, Increased hepatic enzymes, Weight increased.

**MARKETED BY:**



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(Additional information is available on request)