VELOZ FAST

Abbreviated Prescribing information for VELOZ FAST [Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

PHARMACOLOGICAL PROPERTIES: VELOZ FAST contains Rabeprazole Sodium Tablets 20mg (With sodium bicarbonate as buffer). Rabeprazole belongs to a class of antisecretory compounds (substituted benzimidazoles proton-pump inhibitors) that do not exhibit anticholinergic or histamine H2-receptor antagonist properties, but

suppress gastric acid secretion by inhibiting the gastric H^+ , K^+ATP as 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: It is indicated for the treatment of duodenal ulcer, gastric ulcer (GU), Zollinger-Ellison syndrome (ZES) & gastroesophageal reflux disease (GERD).

DOSAGE AND ADMINISTRATION: One Tablet once daily or as directed by the physician. Tablet should be swallowed completely. Do not crush or chew the tablet.

CONTRAINDICATION: Rabeprazole is contraindicated in patients with known hypersensitivity to rabeprazole, substituted benzimidazoles or to any component of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute interstitial nephritis, and urticaria.

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.

DRUGS INTERACTIONS: The cytochrome P450 (CYP450) drug metabolizing enzyme system metabolizes Rabeprazole. 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.

ADVERSE REACTIONS: Common (affect less than 1 in 10 people): Infections, Difficulty sleeping, Headache or feeling dizzy, Cough, runny nose or sore throat (pharyngitis), effects on your stomach or gut such as stomach pain, diarrhoea, wind (flatulence), feeling sick (nausea), being sick (vomiting) or constipation, aches or back pain, weakness or flu-like symptoms, benign polyps in the stomach. Uncommon (affect less than 1 in 100 people): Feeling nervous or drowsy, Chest infection (bronchitis), Painful and blocked sinuses (sinusitis), Dry mouth, Indigestion or belching, Skin rash or

redness, Muscle, leg or joint pain, Fractures of the hip, wrist and spine, Bladder infection (urinary tract infection), Chest pain, Chills or fever, Changes in how your liver is working (shown in blood tests) *Rare (affect less than 1 in 1,000 people:* Loss of appetite (Anorexia), Depression, Hypersensitivity (includes allergic reactions), Visual disturbance, Sore mouth (stomatitis) or taste disturbance, Upset stomach or stomach pain, Liver problems including yellowing of your skin and whites of your eyes (jaundice), Itchy rash or blistering skin, Sweating, Kidney problems, Weight gain, Changes in white blood cells (shown in blood tests) which may result in frequent infection, Reduction in blood platelets resulting in bleeding or bruising more easily than normal, *Other possible side effects (unknown frequency:* Acute kidney injury, Breast swelling in men, Fluid retention, Inflammation of the gut (leading to diarrhoea), Low blood levels of sodium which can cause tiredness and confusion, muscle, Twitching, fits and coma, Patients who have previously had liver problems may very rarely get encephalopathy (a brain disease)" and rash, possibly with pain in the joints.

MARKETED BY:



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(Additional information is available on request)