VELOZ IT

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for VELOZ IT (Rabeprazole Gastro Resistant and ltopride Prolonged Release Capsules IP 20 mg /150 mg**)**

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: *Rabeprazole* sodium belongs to the class of anti-secretory compounds, the substituted benzimidazoles, that do not exhibit anticholinergic or H2 histamine antagonist properties, but suppress gastric acid secretion by the specific inhibition of the H+/K+-ATPase enzyme (the acid or proton pump). *Itopride* activates the gastrointestinal propulsive motility by dopamine D2 receptors antagonistic action and acetylcholine esterase inhibitory action. Itopride activates acetylcholine release and inhibits its degradation. In addition itopride has an antiemetic action which is based on interaction with dopamine D2 receptors in chemoreceptor zone.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician.

CONTRAINDICATION: Contraindicated in patients with known hypersensitivity to Rabeprazole, substituted benzimidazoles, Itopride or to any component of the formulation. Also contraindicated in patients in whom an increase in GI motility could be harmful eg, GI hemorrhage, mechanical obstruction or perforation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute interstitial nephritis, and urticaria.

WARNINGS & PRECAUTIONS: *Rabeprazole:* possibility of malignancy should be excluded prior to commencing treatment with Rabeprazole, blood dyscrasias (thrombocytopenia and neutropenia), Hepatic enzyme abnormalities. Co-administration of atazanavir with Rabeprazole is not recommended. Treatment with proton pump inhibitors, including Rabeprazole, may possibly increase the risk of gastrointestinal infections such as Salmonella, Campylobacter and Clostridium difficile, increase the risk of hip, wrist and spine fracture, predominantly in older people or in presence of other recognised risk factors, Severe hypomagnesaemia. Concomitant use of Rabeprazole with Methotrexate: may elevate and prolong serum levels of methotrexate and/or its metabolite, leading to methotrexate toxicities. Influence on vitamin B12 absorption, Subacute cutaneous lupus erythematosus (SCLE), Interference with laboratory tests: Increased Chromogranin A (CgA). *Itopride:* contraindicated in hypersensitivity to itopride or benzamides; lactation, GI hemorrhage, obstruction or perforation. Itopride may not be indicated for those suffering from Parkinson's disease or other conditions involving dopamine regulation issues. Itopride should be used with special caution in the young and the elderly. It may cause dizziness, do not drive a car or operate machinery while taking this medication.

DRUG INTERACTION: *Rabeprazole sodium:* Coadministration of rabeprazole sodium with ketoconazole or itraconazole may result in a significant decrease in antifungal plasma levels. PPIs, including rabeprazole, should not be co-administered with atazanavir. Methotrexate: may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate. *Itopride:* Anticholinergic drugs may reduce the action of itopride. No interactions detected with warfarin, diazepam, diclofenac, nifedipine and nicardipine. Metabolic interactions are not to be expected because itopride is mainly metabolized by flavin monooxygenase.

ADVERSE REACTIONS: ***Rabeprazole****: 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.

Itopride: Blood and Lymphatic System Disorders: Leukopenia and thrombocytopenia. Immune System Disorders: Anaphylactoid reaction. Endocrine Disorders: Increased prolactin level and gynecomastia. Nervous System Disorders: Dizziness, headache, tremor. Gastrointestinal Disorders: Diarrhea, constipation, abdominal pain, increased saliva, and nausea. Hepatobiliary Disorder: Jaundice. Skin and Subcutaneous Tissue Disorders: Rash, redness, itching. Investigations: Increased AST (SGOT), increased ALT (SGPT), increased γ-GTP, increased alkaline phosphatase and increased bilirubin.

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/VELOZ IT 20, 150mg/Sep-22/07/ABPI
(Additional information is available on request)