VELOZ 20

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

Abbreviated Prescribing information for VELOZ 20 (Rabeprazole Sodium Tablets I.P. (Enteric coated)**)**

[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) The effect is dose-related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus. Animal studies indicate that after administration, rabeprazole sodium rapidly disappears from both the plasma and gastric mucosa. As a weak base, rabeprazole is rapidly absorbed following all doses and is concentrated in the acid environment of the VELOZ 20 al cells. Rabeprazole is converted to the active sulphenamide form through protonation and it subsequently reacts with the available cysteines on the proton pump.

THERAPEUTIC INDICATION: It is indicated for the treatment of Gastroesophageal reflux Disease (deodenal ulcer & ellision syndrome).

DOSAGE AND ADMINISTRATION: As directed by physician. Patients should be cautioned that the VELOZ 20 tablets should not be chewed or crushed, but should be swallowed whole

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. VELOZ 20 is contra-indicated in pregnancy and during breast feeding.

WARNINGS & PRECAUTIONS: Gastric or oesophageal malignancy, therefore the possibility of malignancy should be excluded prior to commencing treatment with VELOZ 20. Patients on long-term treatment (particularly those treated for more than a year) should be kept under regular surveillance. A risk of cross-hypersensitivity reactions with other proton pump inhibitor (PPI) or substituted benzimidazoles cannot be excluded. Patients should be cautioned that VELOZ 20 tablets should not be chewed or crushed, but should be swallowed whole. VELOZ 20 is not recommended for use in children, as there is no experience of its use in this group. There have been post marketing reports of blood dyscrasias (thrombocytopenia and neutropenia). In the majority of cases where an alternative aetiology cannot be identified, the events were uncomplicated and resolved on discontinuation of rabeprazole. Hepatic enzyme abnormalities have been seen in reported clinical trials and have also been reported since market authorisation. In the majority of cases where an alternative aetiology cannot be identified, the events were uncomplicated and resolved on discontinuation of rabeprazole. No evidence of significant drug related safety problems was seen in a study of patients with mild to moderate hepatic impairment versus normal age and sex matched controls. However because there are no clinical data on the use of VELOZ 20 in the treatment of patients with severe hepatic dysfunction the prescriber is advised to exercise caution when treatment with VELOZ 20 is first initiated in such patients. Warning with co-administration of atazanavir with VELOZ 20 is not recommended, Concomitant use of rabeprazole with methotrexate, Influence on vitamin B12 absorption, PPIS are associated with very infrequent cases of Subacute cutaneous lupus erythematosus (SCLE) and interference with laboratory tests

DRUG INTERACTION: Rabeprazole sodium produces a profound and long lasting inhibition of gastric acid secretion. An interaction with compounds whose absorption is ph dependent may occur. Co-administration of rabeprazole sodium with ketoconazole or itraconazole may result in a significant decrease in antifungal plasma levels. Therefore

individual patients may need to be monitored to determine if a dosage adjustment is necessary when ketoconazole or itraconazole are taken concomitantly with VELOZ 20. In reported clinical trials, antacids were used concomitantly with the administration of rabeprazole and, in a specific drug-drug interaction study, no interaction with liquid antacids was observed. Co-administration of atazanavir 300 mg/ritonavir 100 mg with omeprazole (40 mg once daily) or atazanavir 400 mg with lansoprazole (60 mg once daily) to healthy volunteers resulted in a substantial reduction in atazanavir exposure. The absorption of atazanavir is ph dependent. Although not studied, similar results are expected with other ppis. Therefore ppis, including rabeprazole, should not be co-administered with atazanavir. Methotrexate: Case reports, published population pharmacokinetic studies, and retrospective analyses suggest that concomitant administration of ppis and methotrexate (primarily at high dose; see methotrexate prescribing information) may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate. However, no formal drug interaction studies of methotrexate with ppis have been conducted.

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.

Manufactured BY:
Torrent pharmaceuticals Ltd.

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(Additional information is available on request)