VELOZ M

Abbreviated Prescribing information for VELOZ M [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: 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**. Mosapride:** In the gastric emptying test for healthy adults and patients with chronic gastritis, single administration of this drug enhanced gastric emptying. **INDICATIONS:** For the treatment of Gastroesophageal reflux not responding to Rabeprazole alone.

DOSAGE AND ADMINISTRATION: As directed by the physician.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. VELOZ M is contra-indicated in pregnancy and during breast feeding. VELOZ M is contraindicated in the patients with GI hemorrhage, mechanical obstruction, or perforation.

WARNINGS & PRECAUTIONS: **Rabeprazole:** Symptomatic response to therapy with rabeprazole sodium does not preclude the presence of gastric or oesophageal malignancy, therefore the possibility of malignancy should be excluded prior to commencing treatment with VELOZ M. 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. Treatment with PPIs, including VELOZ M, may possibly increase the risk of gastrointestinal infections such as Salmonella, Campylobacter and Clostridium difficile. Influence on vitamin B12 absorption, subacute cutaneous lupus erythematosus (SCLE), Interference with laboratory tests. **Mosapride:** Mosapride citrate (should not be used for more than 2 weeks in patients if no clinically therapeutic outcome is observed. Important Precautions: When this drug is used for the treatment of gastrointestinal symptoms associated with chronic gastritis, after administration for a certain period of time (usually 2 weeks), the gastrointestinal symptoms should be assessed for improvement and the necessity of continuing administration should be evaluated.

DRUGS INTERACTIONS: Rabeprazole: 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 Rabeprazole sodium. No interaction with liquid antacids. rabeprazole, should not be co-administered with atazanavir. Due to the substantial reduction in atazanavir exposure. **Mosapride:** *Erythromycin:* When erythromycin at 1,200 mg/day was concomitantly administered with this drug at 15 mg/day, in comparison with a single administration of mosapride, maximum blood concentration of mosapride increased from 42.1 ng/mL to 65.7 ng/mL, the half-life was prolonged from 1.6 hours to 2.4 hours and AUC_{0-4} increased from 62 ng•hr/mL to 114 ng•hr/mL. (Healthy adult.) *Anticholinergic agents:* There is a possibility that the effect of

this drug may be attenuated. Therefore, in case of the concomitant use of anticholinergic agents, precautions such as taking the drugs at intervals should be taken. As gastroprokinetic effect of this drug is exerted by activation of the cholinergic nerves, concomitant use of anticholinergic agents may decrease the effect of this drug.

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. **Mosapride:** In different clinical trials, adverse reactions were observed in 40 (4.0%) out of 998 patients. The main adverse reactions were diarrhea/loose stools (1.8%), dry mouth (0.5%), malaise (0.3%), etc. Abnormal laboratory values were observed in 30 (3.8%) of 792 cases and included increased eosinophils (1.1%), triglycerides (1.0%), SGOT, SGPT, ALP and □-GTP (0.4% each). Gastrointestinal Diarrhea/ loose stools, dry mouth, abdominal pain. Hepatic Increased SGOT, SGPT, ALP, □-GTP Cardiovascular Palpitation Others Malaise, dizziness/ light-headed feeling, eosinophilia, increased triglycerides

MARKETED BY:

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IN/VELOZ M /Nov-20/01 /ABPI

(Additional information is available on request)