

## VELOZ L

Abbreviated Prescribing information for VELOZ L [Enteric Coated Rabeprazole Sodium and Levosulpiride Sustained Release Capsules]

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION: Rabeprazole** Rabeprazole sodium belongs to the class of anti-secretory compounds, the substituted benzimidazoles, that do not exhibit anticholinergic or H<sub>2</sub> histamine antagonist properties but suppress gastric acid secretion by the specific inhibition of the H<sup>+</sup>/K<sup>+</sup>-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 parietal cells. Rabeprazole is converted to the active sulphenamide form through protonation, and it subsequently reacts with the available cysteines on the proton pump. **Levosulpiride** : Levosulpiride is selective blocks D<sub>2</sub> receptors at the submucosal and myenteric plexus peripheral level, the selective antagonistic action of levosulpiride on the D<sub>2</sub> receptors also makes it useful as a prokinetic drug. In the gastric emptying test for healthy adults and patients with chronic gastritis, single administration of this drug enhanced gastric emptying.

**INDICATIONS:** It is indicated for the treatment of Gastro-esophageal reflux disease (GERD).

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

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients. Pregnancy and during breast feeding. Parkinson disease. History of epilepsy

**WARNINGS & PRECAUTIONS:** If 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 L 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 B<sub>12</sub> and receive long term treatment with rabeprazole sodium. As with all acid reducing agents, rabeprazole sodium may lead to a reduced absorption of vitamin B<sub>12</sub>. If you have ever had a skin reaction after treatment with a medicine similar to VELOZ L 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

L. Remember to also mention any other ill- effects like pain in your joints. You are due to have a specific blood test (Chromogranin A). If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using VELOZ L.

**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 VELOZ L. **Levosulpiride:** Antacids and Sucralfate: They can decrease the absorption of the drug. Alcohol: there is increased chance of sedation. Smoking: increased metabolism of the drug may require higher dose. Antihypertensive medications: concomitant use may enhance the hypotensive effect seen with the drug. Anticholinergics: increased incidence of anticholinergic side effects. Levo dopa: It may oppose the antipsychotic action of the drug. Arrhythmia especially prolonged QT interval with the concurrent use of Atomoxetine, Antiarrhythmics.

**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. **Levosulpiride:** Acute muscular dystonia characterized by abnormal movements (twitching, tremor etc.) of hands, leg, tongue and facial muscles. Sedation or increase in plasma prolactin levels manifested by breast enlargement, production of milk and stopping of menstrual periods. This can be taken care of with the use of lower dose of this drug. Neuroleptic malignant syndrome (characterized by hyperpyrexia, muscle rigidity, increased myoglobin and creatine kinase; the last two suggestive of muscle damage. Akathisia Tardive dyskinesia, Postural hypotension (because of autonomic blockade), tolerance develops to this effect after some time. Elevated liver transaminases.

MARKETED BY:

**TORRENT**  
PHARMA

TORRENT PHARMACEUTICALS LTD.

**IN/VELOZ L/20,75mg/FEB-26/07/ABPI**

(Additional information is available on request)