

VELOZ D

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only
Abbreviated prescribing information for VELOZ D (Rabeprazole sodium and Domperidone sustained release capsules 20 mg+30 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

MECHANISM OF ACTION: *Rabeprazole:* 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 Dal cells. Rabeprazole is converted to the active sulphenamide form through protonation and it subsequently reacts with the available cysteines on the proton pump. *Domperidone:* Domperidone is a dopamine antagonist with anti-emetic properties. Domperidone does not readily cross the blood-brain barrier. In domperidone users, especially adults, extrapyramidal side effects are very rare, but domperidone promotes the release of prolactin from the pituitary. Its anti-emetic effect may be due to a combination of peripheral (gastrokinetic) effects and antagonism of dopamine receptors in the chemoreceptor trigger zone, which lies outside the blood-brain barrier in the area postrema. Animal studies, together with the low concentrations found in the brain, indicate a predominantly peripheral effect of domperidone on dopamine receptors. Studies in man have shown oral domperidone to increase lower oesophageal pressure, improve antroduodenal motility and accelerate gastric emptying. There is no effect on gastric secretion.

INDICATION: For the treatment of Gastroesophageal reflux not responding to Rabeprazole alone.

DOSAGE AND ADMINISTRATION: One capsule once daily preferably before meal or as directed by physician.

CONTRAINDICATION: Veloz D is contraindicated in the following situations: Known hypersensitivity to active substance or any of the excipients, Prolactin-releasing pituitary tumour (prolactinoma), when stimulation of the gastric motility could be harmful e.g in patients with gastro-intestinal haemorrhage, mechanical obstruction or perforation, in patients with moderate or severe hepatic impairment, in patients who have known existing prolongation of cardiac conduction intervals, particularly QTc, patients with significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure, co-administration with QT-prolonging drugs, at the exception of apomorphine, co-administration with potent CYP3A4 inhibitors (regardless of their QT prolonging effects) and pregnancy and during breast feeding.

WARNINGS & PRECAUTIONS: *Rabeprazole:* Co-administration of atazanavir with rabeprazole is not recommended, Treatment with PPIs, including rabeprazole, may possibly increase the risk of gastrointestinal infections such as Salmonella, Campylobacter and Clostridium difficile, Concomitant use of rabeprazole with methotrexate, Influence on vitamin B12 absorption, Subacute cutaneous lupus erythematosus (SCLE) and Interference with laboratory tests. *Domperidone:* Cardiovascular effects, use with apomorphine, Use in infants and with Renal impairment.

DRUG INTERACTIONS: Do not take VELOZ D if you are taking medicine to treat: Fungal infections such as azole anti-fungals, specifically oral ketoconazole, fluconazole or voriconazole.

Bacterial infections, specifically erythromycin, clarithromycin, telithromycin, moxifloxacin, pentamidine (these are antibiotics). Heart problems or high blood pressure (e.g., amiodarone, dronedarone, quinidine, disopyramide, dofetilide, sotalol, diltiazem, verapamil), Psychoses (e.g., haloperidol, pimozide, sertindole), Depression (e.g., citalopram, escitalopram), Gastro-intestinal disorders (e.g., cisapride, dolasetron, prucalopride), Allergy (e.g., mequitazine, mizolastine) Malaria (in particular halofantrine), AIDS/HIV (protease inhibitors), Cancer (e.g., toremifene, vandetanib, vincamine) and Atazanavir– used to treat HIV-infection. VELOZ D may lower the amount of this type of medicine in your blood and they should not be used together. Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your VELOZ D treatment. Tell your doctor or pharmacist if you are taking drugs to treat infection, heart problems or AIDS/HIV.

ADVERSE REACTIONS: *Common (affects less than 1 in 10 people):* Dry mouth, 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 and Benign polyps in the stomach. *Uncommon (affects less than 1 in 100 people):* Lowering of sexual drive (libido) in men, Feeling anxious, Feeling drowsy, Headaches, Diarrhoea, Itchy skin, Unusual production of breast milk in men and women, Painful or tender breasts, A general feeling of weakness, Chest infection (bronchitis), Painful and blocked sinuses (sinusitis), Indigestion or belching, Muscle, leg or joint pain, Fractures of the hip, wrist and spine, Bladder infection (urinary tract infection), Chest pain, Chills or fever and Changes in how your liver is working (shown in blood tests). *Not known (Frequency cannot be estimated from the available data):* Disorders of the cardiovascular system, Feeling agitated or irritable, Feeling more nervous than usual, Abnormal eye movements, Inability to urinate, Breast enlargement in men and In women, menstrual periods may be irregular or stop. *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, Sweating, Acute Kidney injury, Weight gain, Changes in white blood cells (shown in blood tests) which may result in frequent infection and Reduction in blood platelets resulting in bleeding or bruising more easily than normal. *Other possible side effects (unknown frequency):* 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)”, Kidney injury and Rash, possibly with pain in the joints.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)