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

VELOZ FAST

1. **Generic Name**

   Rabeprazole Sodium Tablets 20mg (With sodium bicarbonate as buffer)

2. Qualitative and quantitative composition

Each uncoated tablet contains:
Rabeprazole Sodium IP… 20 mg
(With sodium bicarbonate as buffer)
Colour: Red oxide of Iron.
Excipients: Sodium Bicarbonate, Magnesium oxide, Colloidal Silicon dioxide, Crospovidone XL-10, Ferric oxide Red, Ethyl cellulose, Isopropyl alcohol, Microcrystalline cellulose, Talc, Aspartame, Powdarome Orange Premium, Magnesium stearate, Mannitol, Magnesium oxide, Low-substituted Hydroxypropyl cellulose, Povidone, Sodium Hydroxide, Hydroxypropylmethyl cellulose and Propylene glycol.

3. Dosage form and strength

Dosage form: Tablet

Strength: 20 mg

4. Clinical particulars

4.1 Therapeutic indication

It is indicated for the treatment of duodenal ulcer, gastric ulcer (GU), Zollinger-Ellison syndrome (ZES) & gastroesophageal reflux disease (GERD).

4.2 Posology and method of administration

One Tablet once daily.
Tablet should be swallowed whole. Do not crush or chew the tablet.

4.3 Contraindications

Rabeprazole is contraindicated in patients with known hypersensitivity to rabeprazole, substituted benzimidazoles or to any component of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute interstitial nephritis, and urticaria.

4.4 Special warnings and precautions for use

Presence of Gastric Malignancy

Symptomatic response to therapy with rabeprazole does not preclude the presence of gastric malignancy.

Patients with healed GERD were treated for up to 40 months with rabeprazole and monitored with serial gastric biopsies. In a reported study, patients without *H. pylori* infection (221 of 326 patients) had no clinically important pathologic changes in the gastric mucosa. Patients with *H. pylori* infection at baseline (105 of 326 patients) had mild or moderate inflammation in the gastric body or mild inflammation in the gastric

antrum. Patients with mild grades of infection or inflammation in the gastric body tended to change to moderate, whereas those graded moderate at baseline tended to remain stable. Patients with mild grades of infection or inflammation in the gastric antrum tended to remain stable. At baseline, 8% of patients had atrophy of glands in the gastric body and 15% had atrophy in the gastric antrum. At endpoint, 15% of patients had atrophy of glands in the gastric body and 11% had atrophy in the gastric antrum. Approximately 4% of patients had intestinal metaplasia at some point during follow-up, but no consistent changes were seen.

Concomitant Use with Warfarin

Steady state interactions of rabeprazole and warfarin have not been adequately evaluated in patients. There have been reports of increased INR and prothrombin time in patients receiving a proton pump inhibitor and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with a proton pump inhibitor and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time.

Acute Interstitial Nephritis

Acute interstitial nephritis has been observed in patients taking PPIs including Rabeprazole. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue Rabeprazole if acute interstitial nephritis develops.

Cyanocobalamin (vitamin B-12) Deficiency

Daily treatment with any acid-suppressing medications over a long period of time (e.g., longer than 3 years) may lead to malabsorption of cyanocobalamin (vitamin B-12) caused by hypo-or achlorhydria. Rare reports of cyanocobalamin deficiency occurring with acid-suppressing therapy have been reported in the literature. This diagnosis should be considered if clinical symptoms consistent with cyanocobalamin deficiency are observed.

Clostridium difficile Associated Diarrhea

Published observational studies suggest that PPI therapy like Rabeprazole may be associated with an increased risk of *Clostridium difficile* associated diarrhea, especially in hospitalized patients. This diagnosis should be considered for diarrhea that does not improve.
Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated.
Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents. For more information specific to antibacterial agents (clarithromycin and amoxicillin) indicated for use in combination with Rabeprazole.

Bone Fracture

Several published observational studies in adults suggest that PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use

the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to established treatment guidelines.

Hypomagnesemia/

Hypomagnesemia, symptomatic and asymptomatic, has been reported rarely in patients treated with PPIs for at least three months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures. In most patients, treatment of hypomagnesemia required magnesium replacement and discontinuation of the PPI.
For patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that may cause hypomagnesemia (e.g., diuretics), healthcare professionals may consider monitoring magnesium levels prior to initiation of PPI treatment and periodically.

Concomitant Use of Rabeprazole with Methotrexate

Literature suggests that concomitant use of PPIs with methotrexate may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. In high-dose methotrexate administration, a temporary withdrawal of the PPI may be considered in some patients.

4.5 Drugs interactions

Drugs Metabolized by CYP450

Rabeprazole is metabolized by the cytochrome P450 (CYP450) drug metabolizing enzyme system. Studies in healthy subjects have shown that rabeprazole does not have clinically significant interactions with other drugs metabolized by the CYP450 system, such as warfarin and theophylline given as single oral doses, diazepam as a single intravenous dose, and phenytoin given as a single intravenous dose (with supplemental oral dosing). Steady state interactions of rabeprazole and other drugs metabolized by this enzyme system have not been studied in patients.

Warfarin

There have been reports of increased INR and prothrombin time in patients receiving proton pump inhibitors, including rabeprazole, and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death**.**

Cyclosporine

In vitro incubations employing human liver microsomes indicated that rabeprazole inhibited cyclosporine metabolism with an IC50 of 62 micromolar, a concentration that is over 50 times higher than the Cmax in healthy volunteers following 14 days of dosing with 20 mg of rabeprazole. This degree of inhibition is similar to that by omeprazole at equivalent concentrations.

Compounds Dependent on Gastric pH for Absorption

Due to its effects on gastric acid secretion, rabeprazole can reduce the absorption of drugs where gastric pH is an important determinant of their bioavailability. Like with other drugs that decrease the intragastric acidity, the absorption of drugs such as ketoconazole, atazanavir, iron salts, erlotinib, and mycophenolate mofetil (MMF) can

decrease, while the absorption of drugs such as digoxin can increase during treatment with Rabeprazole.

Drugs Metabolized by CYP2C19

In a clinical study in Japan evaluating rabeprazole in adult patients categorized by CYP2C19 genotype (n=6 per genotype category), gastric acid suppression was higher in poor metabolizers as compared to extensive metabolizers. This could be due to higher rabeprazole plasma levels in poor metabolizers. Whether or not interactions of rabeprazole sodium with other drugs metabolized by CYP2C19 would be different between extensive metabolizers and poor metabolizers has not been studied.

Combined Administration with Clarithromycin

Combined administration consisting of rabeprazole, amoxicillin, and clarithromycin resulted in increases in plasma concentrations of rabeprazole and 14-hydroxyclarithromycin.
Concomitant administration of clarithromycin with other drugs can lead to serious adverse reactions due to drug interactions. Because of these drug interactions, clarithromycin is contraindicated for co-administration with certain drugs.

Methotrexate

Case reports, published population pharmacokinetic studies, and retrospective analyses suggest that concomitant administration of PPIs and methotrexate may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxy methotrexate. However, no formal drug interaction studies of methotrexate with PPIs have been conducted.

Clopidogrel

Concomitant administration of rabeprazole and clopidogrel in healthy subjects had no clinically meaningful effect on exposure to the active metabolite of clopidogrel. No dose adjustment of clopidogrel is necessary when administered with an approved dose of Rabeprazole.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

Pregnancy Category C

Risk Summary

There are no adequate and well-controlled studies with Rabeprazole in pregnant women. No evidence of teratogenicity was seen in animal reproduction studies with rabeprazole at 13 and 8 times the human exposure at the recommended dose for GERD, in rats and rabbits, respectively. Changes in bone morphology were observed in offspring of rats treated with oral doses of a different PPI through most of pregnancy and lactation. Because of these findings, Rabeprazole should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known if Rabeprazole is excreted in human milk; however, rabeprazole is present in rat milk. Because many drugs are excreted in milk, caution should be exercised when Rabeprazole is administered to a nursing woman.

Pediatric Use

Symptomatic GERD in Adolescent Patients Greater or Equal to 12 Years of Age
In a reported multicenter, randomized, open-label, parallel-group study, 111 adolescent patients 12 to 16 years of age with a clinical diagnosis of symptomatic GERD, or suspected or endoscopically proven GERD, were randomized and treated with either Rabeprazole once daily for up to 8 weeks for the evaluation of safety and efficacy. The adverse event profile in adolescent patients was similar to that of adults. The related reported adverse reactions that occurred in ≥2% of patients were headache (5.4%) and nausea (1.8%). There were no adverse reactions reported in these studies that were not previously observed in adults.

GERD in Pediatric Patients 1 to 11 Years of Age
The use of Rabeprazole for treatment of GERD in pediatric patients 1 to 11 years of age is supported by a randomized, multicenter, double-blind clinical trial which evaluated two dose levels of rabeprazole in 127 pediatric patients with endoscopic and histologic evidence of GERD prior to study treatment. Dosing was determined by body weight: Patients weighing 6.0 to 14.9 kg received either 5 or 10 mg and those weighing 15.0 kg or more received 10 or 20 mg of Rabeprazole Sprinkle daily. After 12 weeks of rabeprazole treatment, 81% of patients demonstrated esophageal mucosal healing on endoscopic assessment. In patients who had esophageal mucosal healing at 12 weeks and elected to continue for 24 more weeks of rabeprazole, 90% retained esophageal mucosal healing at 36 weeks. No prespecified formal hypothesis testing for evaluation of efficacy was conducted. The absence of a placebo group does not allow assessment of sustained efficacy through 36 weeks. There were no adverse reactions reported in this study that were not previously observed in adolescents or adults.

Geriatric Use

Of the total number of subjects in clinical studies of Rabeprazole, 19% were 65 years and over, while 4% were 75 years and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Gender

Duodenal ulcer and erosive esophagitis healing rates in women are similar to those in men. Adverse reactions and laboratory test abnormalities in women occurred at rates similar to those in men.

4.7 Effects on ability to drive and use machines

Based on the pharmacodynamic properties and the adverse events profile, it is unlikely that VELOZ FAST would cause an impairment of driving performance or compromise

the ability to use machinery. If however, alertness is impaired due to somnolence, it is recommended that driving and operating complex machinery be avoided.

4.8 Undesirable effects

The most commonly reported adverse drug reactions, during controlled clinical trials with rabeprazole were headache, diarrhoea, abdominal pain, asthenia, flatulence, rash and dry mouth. The majority of adverse events experienced during clinical studies were mild or moderate in severity, and transient in nature. There have been reports of thrombocytopenia, neutropenia and leukopenia. Bullous eruptions have been reported and other dermatological reactions including erythema have been reported. Treatment should be stopped immediately at the recurrence of skin lesions.
The following adverse events have been reported from clinical trial and post-marketed experience

System Organ	Common	Uncommon	Rare	Very Rare	Not known
Infections and	Infection				
Blood and lymphatic			Neutropenia Leucopenia Thrombocytopenia Leucocytosis		
Immune system			Hypersensitivity		
Metabolism and nutrition			Anorexia		Hyponatremia Hypomagnesae
Psychiatric	Insomnia	Nervousness	Depression		Confusion
Nervous system	Headache	Somnolence			
Eye disorders			Visual disturbance		
Vascular					Peripheral oedema
Respiratory, thoracic and mediastina	Cough Pharyngitis Rhinitis	Bronchitis Sinusitis			
Gastrointestinal disorders	Diarrhoea Vomiting Nausea Abdominal pain Constipation Flatulence Fundic	Dyspepsia Dry mouth Eructation	Gastritis Stomatitis Taste disturbance		Microscopic colitis

	polyps (benign)				
Hepatobiliary disorders			Hepatitis Jaundice Hepatic encephalopathy		
Skin and subcutaneous tissue disorders		Rash Erythema	Pruritus Sweating Bullous reactions	Erythema multiforme, toxic epidermal necrolysis (TEN), Stevens-	Subacute cutaneous lupus erythematosus
Musculoskeletal and connective tissue disorders	Non-specific pain Back pain	Myalgia Leg cramps Arthralgia Fracture of the hip,wrist or			
Renal and urinary disorders		Urinary tract infection	Interstitial nephritis		Acute Kidney Injury

Reproductive system and breast disorders					Gynecomastia
General disorders and administration site conditions	Asthenia Influenza like illness	Chest pain Chills Pyrexia			
Investigations		Increased hepatic enzymes	Weight increased		

Reporting of adverse events

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://torrentpharma.com/index.php/site/info/adverse_event_reporting. By reporting side effects, you can help provide more information on the safety of this medicine**.**

4.9 Overdose

Because strategies for the management of overdose are continually evolving, it is advisable to contact a Poison Control Center to determine the latest recommendations for the management of an overdose of any drug. There has been no experience with large overdoses with rabeprazole. Seven reports of accidental overdosage with rabeprazole have been received. The maximum reported overdose was 80 mg. There were no clinical signs or symptoms associated with any reported overdose. Patients with Zollinger-Ellison syndrome have been treated with up to 120 mg rabeprazole QD. No specific antidote for rabeprazole is known. Rabeprazole is extensively protein bound and is not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive.

Single oral doses of rabeprazole at 786 mg/kg and 1024 mg/kg were lethal to mice and rats, respectively. The single oral dose of 2000 mg/kg was not lethal to dogs. The major symptoms of acute toxicity were hypoactivity, labored respiration, lateral or prone position, and convulsion in mice and rats and watery diarrhea, tremor, convulsion, and coma in dogs.

5. Pharmacological properties

5.1 Mechanism of Action

Rabeprazole belongs to a class of antisecretory compounds (substituted benzimidazoles proton-pump inhibitors) that do not exhibit anticholinergic or histamine H2-receptor antagonist properties, but suppress gastric acid secretion by inhibiting the gastric H^+, K^+ATPase at the secretory surface of the gastric parietal cell. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, rabeprazole has been characterized as a gastric proton-pump inhibitor. Rabeprazole blocks the final step of gastric acid secretion.

In gastric parietal cells, rabeprazole is protonated, accumulates, and is transformed to an active sulfenamide. When studied *in vitro*, rabeprazole is chemically activated at pH 1.2 with a half-life of 78 seconds. It inhibits acid transport in porcine gastric vesicles with a half-life of 90 seconds.

5.2 Pharmacodynamic properties

Pharmacotherapeutic group: Alimentary tract and metabolism, Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD), proton pump inhibitors, ATC code: A02B C04

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 parietal cells. Rabeprazole is converted to the active sulphenamide form through protonation and it subsequently reacts with the available cysteines on the proton pump. Anti-secretory Activity: After oral administration of a 20mg dose of rabeprazole sodium the onset of the anti-secretory effect occurs within one hour, with the maximum effect occurring within two to four hours. Inhibition of basal and food stimulated acid secretion 23 hours after the first dose of rabeprazole sodium are 69% and 82% respectively and the duration of inhibition lasts up to 48 hours. The inhibitory effect of rabeprazole sodium on acid secretion increases slightly with repeated once-daily dosing, achieving steady state inhibition after three days. When the drug is discontinued, secretory activity normalises over 2 to 3 days.

Decreased gastric acidity due to any means, including proton pump inhibitors such as rabeprazole, increases counts of bacteria normally present in the gastrointestinal tract. Treatment with proton pump inhibitors may possibly increase the risk of gastrointestinal infections such as *Salmonella*, *Campylobacter* and *Clostridium difficile*.

Serum Gastrin Effects: In clinical studies patients were treated once daily with 10 or 20mg rabeprazole sodium, for up to 43 months duration. Serum gastrin levels increased during the first 2 to 8 weeks reflecting the inhibitory effects on acid secretion and remained stable while treatment was continued. Gastrin values returned to pre-treatment levels, usually within 1 to 2 weeks after discontinuation of therapy. Human gastric biopsy specimens from the antrum and the fundus from over 500 patients receiving rabeprazole or comparator treatment for up to 8 weeks have not detected changes in ECL cell histology, degree of gastritis, incidence of atrophic gastritis, intestinal metaplasia or distribution of H. pylori infection. In over 250 patients followed for 36 months of continuous therapy, no significant change in findings present at baseline was observed.

Other Effects: Systemic effects of rabeprazole sodium in the CNS, cardiovascular and respiratory systems have not been found to date. Rabeprazole sodium, given in oral doses of 20mg for 2 weeks, had no effect on thyroid function,
carbohydrate metabolism, or circulating levels of parathyroid hormone, cortisol, oestrogen, testosterone, prolactin, cholecystokinin, secretin, glucagon, follicle stimulating hormone (FSH), luteinising hormone (LH), renin, aldosterone
or somatotrophic hormone. Studies in healthy subjects have shown that rabeprazole sodium does not have clinically significant interactions with
amoxicillin. Rabeprazole does not adversely influence plasma concentrations of amoxicillin or clarithromycin when co administered for the purpose of eradicating upper gastrointestinal H. pylori infection.

5.3 Pharmacokinetic properties

Absorption:

Absolute bioavailability for a 20 mg oral tablet of rabeprazole (compared to intravenous administration) is approximately 52%.
After oral administration to healthy adults of 10 mg Rabeprazole granules sprinkled on applesauce under fasting condition, median time (Tmax) to peak plasma concentrations (Cmax) of rabeprazole was 2.5 hours and ranged 1.0 to 6.5 hours. The plasma half-life of rabeprazole ranges from 1 to 2 hours.
When 10 mg Rabeprazole granules administered under fasting conditions to healthy adults on one Tablespoon (15 mL) of applesauce, one Tablespoon (15mL) of yogurt, or when mixed with a small amount (5 mL) of liquid infant formula, the type of soft food did not significantly affect Tmax, Cmax, and AUC of rabeprazole.

Distribution:

Rabeprazole is 96.3% bound to human plasma proteins.

Metabolism:

Rabeprazole is extensively metabolized. A significant portion of rabeprazole is metabolized via systemic nonenzymatic reduction to a thioether compound. Rabeprazole is also metabolized to sulphone and desmethyl compounds via cytochrome P450 in the liver. The thioether and sulphone are the primary metabolites measured in human plasma. These metabolites were not observed to have significant antisecretory activity. *In vitro* studies have demonstrated that rabeprazole is metabolized in the liver primarily by cytochromes P450 3A (CYP3A) to a sulphone metabolite and cytochrome

P450 2C19 (CYP2C19) to desmethyl rabeprazole. CYP2C19 exhibits a known genetic polymorphism due to its deficiency in some sub-populations (e.g. 3 to 5% of Caucasians and 17 to 20% of Asians). Rabeprazole metabolism is slow in these sub-populations, therefore, they are referred to as poor metabolizers of the drug.

Elimination:

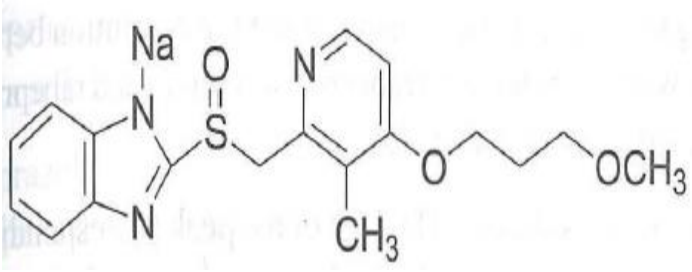
Following a single 20 mg oral dose of ^{14}C-labeled rabeprazole, approximately 90% of the drug was eliminated in the urine, primarily as thioether carboxylic acid, its glucuronide, and mercapturic acid metabolites. The remainder of the dose was recovered in the feces. Total recovery of radioactivity was 99.8%. No unchanged rabeprazole was recovered in the urine or feces.

6. Nonclinical properties

There are no adequate and well-controlled studies with Rabeprazole in pregnant women. No evidence of teratogenicity was seen in animal reproduction studies with rabeprazole at 13 and 8 times the human exposure at the recommended dose for GERD, in rats and rabbits, respectively. Changes in bone morphology were observed in offspring of rats treated with oral doses of a different PPI through most of pregnancy and lactation. Because of these findings, Rabeprazole should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

7. Description

Rabeprazole Sodium is a proton pump inhibitor. Rabeprazole Sodium chemically is 2-({[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]methyl}sulfinyl)-1*H*–benzimidazole sodium. It is a white to light yellow crystalline powder. It is soluble in water. Its chemical formula is $C_{18}H_{20}N_3O_3S$,Na the molecular weight is 381.4 g/mol and the chemical structure is:



VELOZ FAST is Pink coloured, mottled, capsule shaped, uncoated tablets plain on both sides with characteristic odour. Excipient include Sodium Bicarbonate, Magnesium oxide, Colloidal Silicon dioxide, Crospovidone XL-10, Ferric oxide Red, Ethyl cellulose, Isopropyl alcohol, Microcrystalline cellulose, Talc, Aspartame, Powdarome Orange Premium, Magnesium stearate, Mannitol, Magnesium oxide, Low-substituted Hydroxypropyl cellulose, Povidone, Sodium Hydroxide, Hydroxypropylmethyl cellulose and Propylene glycol

8. Pharmaceutical particulars

8.1 Incompatibilities

None

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

Available in blister pack of 10 Tablets**.**

8.4 Storage and handing instructions

Store at temperature not exceeding 25°C. Protect from light and moisture.

Keep all medicines out of reach of children**.**

9. Patient counselling information

9.1 What VELOZ FAST is and what it is used for

9.2 What you need to know before you take VELOZ FAST

9.3 How to take VELOZ FAST

9.4 Possible side effects

9.5 How to store VELOZ FAST

9.6 Contents of the pack and other information

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet. You may need to read it again.

• If you have any further questions, ask your doctor or pharmacist.

• **This medicine has been prescribed for you only.** Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

• If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

9.1.What VELOZ FAST is and what it is used for

VELOZ FAST tablets contain the active ingredient rabeprazole sodium. This belongs to a group of medicines called 'Proton Pump Inhibitors' (PPIs). They work by lowering the amount of acid that your stomach produces.

It is indicated for the treatment of duodenal ulcer, gastric ulcer (GU), Zollinger-Ellison syndrome (ZES) & gastroesophageal reflux disease (GERD).

9.2.What you need to know before you take VELOZ FAST

Do not use VELOZ FAST

You are allergic (hypersensitive) to rabeprazole sodium, or any of the other ingredients of this medicine

- You are pregnant or think that you are pregnant

- You are breast feeding

Do not use **VELOZ FAST** if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using **VELOZ FAST**

Warnings and precautions

Talk to your doctor or pharmacist before taking **VELOZ FAST** 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 FAST** 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 B12 and receive long term treatment with rabeprazole sodium. As with all acid reducing agents, rabeprazole sodium may lead to a reduced absorption of vitamin B12.

- If you have ever had a skin reaction after treatment with a medicine similar to **VELOZ FAST** 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 FAST**. 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 FAST**.

Children

VELOZ FAST should not be used in children.

If you experience severe (watery or bloody) diarrhoea with symptoms such as fever, abdominal pain or tenderness, stop taking **VELOZ FAST** and see a doctor straight away.

Taking a proton pump inhibitor like **VELOZ FAST**, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Other medicines and VELOZ FAST

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole or itraconazole – used to treat infections caused by a fungus. **VELOZ FAST** may lower the amount of this type of medicine in your blood. Your doctor may need to adjust your dose.

- Atazanavir– used to treat HIV-infection. **VELOZ FAST** 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 FAST** treatment.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using **VELOZ FAST**.

Pregnancy, breast feeding and fertility

- Do not use **VELOZ FAST** if you are pregnant or think you may be pregnant

- Do not use **VELOZ FAST** if you are breast-feeding or planning to breast-feed

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You may feel sleepy while taking **VELOZ FAST**. If this happens, do not drive or use any tools or machines.

9.3.How to take VELOZ FAST

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Only remove a tablet from the blister strip when it is time to take your medicine.

- Swallow your tablets whole with a drink of water. Do not chew or crush the tablets.

- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your

condition.

- If you are taking this medicine for a long time, your doctor will want to monitor you.

Adults and older people

For ‘gastro-oesophageal reflux disease’ (GERD)

Treatment of moderate to severe symptoms (symptomatic GERD) - The usual dose will be decided by

If you take more **VELOZ FAST** than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If VELOZ FAST you forget to take

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual

- If you forget to take your medicine for more than 5 days, talk to your doctor before taking any more medicine

- Do not take a double dose (two doses at the same time) to make up for a forgotten dose

If you stop taking VELOZ FAST

Relief of symptoms will normally occur before the ulcer has completely healed. It is important that you do not stop taking the tablets until told to do so by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

9.4.Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects are usually mild and improve without you having to stop taking this medicine.

Stop taking **VELOZ FAST** and see a doctor straight away if you notice any of the following side effects - you may need urgent medical treatment:

- Allergic reactions – the signs may include sudden swelling of your face, difficulty breathing or low blood pressure which may cause fainting or collapse

- Frequent infections, such as a sore throat or high temperature (fever), or ulcers in your mouth or throat

- Bruising or bleeding easily

These side effects are **rare (affect less than 1 in 1,000 people).**

- Severe skin blistering, or soreness or ulcers in your mouth and throat

These side effects are **very rare (affect less than 1 in 10, 000 people).**

Other possible side effects:

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)

- 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)"

- Rash, possibly with pain in the joints

If you are on **VELOZ FAST** for more than three months it is possible that the levels of magnesium in your blood may fall.

Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide toperform regular blood tests to monitor your levels of magnesium.

Do not be concerned by this list of side effects. You may not get any of them.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://torrentpharma.com/index.php/site/info/adverse_event_reporting. By reporting side effects, you can help provide more information on the safety of this medicine.

9.5. How to store VELOZ FAST

Store at temperature not exceeding 25°C. Protect from light and moisture

Keep all medicines out of reach of children.

9.6. Contents of the pack and other information

Each uncoated tablet contains:

Rabeprazole Sodium IP 20 mg

(With sodium bicarbonate as buffer)

Colour: Red oxide of Iron.

The excipients used are Sodium Bicarbonate, Magnesium oxide, Colloidal Silicon dioxide, Crospovidone XL-10, Ferric oxide Red, Ethyl cellulose, Isopropyl alcohol, Microcrystalline cellulose, Talc, Aspartame, Powdarome Orange Premium, Magnesium stearate, Mannitol, Magnesium oxide, Low-substituted Hydroxypropyl cellulose, Povidone, Sodium Hydroxide, Hydroxypropylmethyl cellulose and Propylene glycol.

10. Details of manufacturer

TORRENT PHARMACEUTICALS LTD.

32 No. Middle Camp, NH – 10,

East District, Gangtok, Sikkim – 737 135

11. Details of permission or licence number with date

M/563/2010 dated 13.11.2020

12. Date of revision

Not applicable

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/VELOZ FAST /Nov-20/01 /PI