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

VELOZ INJECTION (LYOPHILIZED)

1. Generic Name

Rabeprazole Sodium Injection I.P.

2. Qualitative and quantitative composition

Each carton contains:
(A) Each vial contains Rabeprazole sodium I.P. 20 mg (As lyophilized Powder)
(B) Each ampoule contains: Sterile water for Injecton IP q.s. to 5 ml
The Excipients used are Di sodium E.D.T.A, glycine, sodium hydroxide, and mannitol.

3. Dosage form and strength

Dosage Form: Injection Vial

Strength: 20 mg

4. Clinical particulars

4.1 Therapeutic indication

For the short-term treatment of gastric and duodenal ulcer, Gastroesophageal reflux Disease (GERD) as an alternative to oral therapy in patients who are unable to take oral proton pump inhibitors.

4.2 Posology and method of administration

Parenteral routes of administration other than intravenous are not recommended. No dosages adjustment is necessary in elderly patients, in patients with renal disease or in patients with mild to moderate hepatic impairment. The recommended adult dose, as an alternative to continue oral therapy, is 20 mg rabeprazole given once daily by intravenous bolus injection or by intravenous infusion for 7 to 10 days.

Veloz injection should be reconstituted with 5 ml of Sterile Water for Injection IP (provided with this pack) and administered as IV Bolus slowly over a period of 15 minutes. For Intravenous infusion, Veloz injection should be reconstituted with 5ml of Sterile Water for Injection I.P. and further diluted with 100 ml of 0.9% Sodium Chloride Injection I.P. or 5% Dextrose Injection I.P. or compound sodium lactate injection I.P. to a final concentration of approximately 0.2 mg/ ml. The intravenous line should always be flushed with either 0.9% sodium chloride injection I.P., compound sodium lactate injection I.P. or 5% Dextrose Injection I.P. both prior to and after administration of Veloz injection. After reconstitution, the intravenous infusion solution should be administered as soon as possible over a period of 10 to 30 minutes. (From the in-house compatibility study, it was found that the reconstituted solution is stable (in 100 ml) for up to 2 hours in 0.9% sodium chloride Injection I.P. and 1 hour for 5% Dextrose Injection I.P. and compound sodium lactate injection I.P. in room temperature. The pH of the reconstituted infusion solution is in the range of 9.0 to 10.5 approximately).

4.3 Contraindications

Rabeprazole is contraindicated in patients with known hypersensitivity to rabeprazole, or to any component of the formulation. RABEPRAZOLE is contra-indicated in pregnancy and during breast-feeding.

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 or oesophageal malignancy.

Patients with healed GERD were treated for up to 40 months with rabeprazole and monitored with serial gastric biopsies. 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.

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.

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 (primarily at high dose) 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.

Concomitant treatment with rabeprazole (20 mg daily) and ketoconazole in healthy subjects decreased the bioavailability of ketoconazole by 30% and increased the AUC and Cmax for digoxin by 19% and 29%, respectively. Therefore, patients may need to be monitored when such drugs are taken concomitantly with rabeprazole. Co-administration of rabeprazole and antacids produced no clinically relevant changes in plasma rabeprazole concentrations.

Concomitant use of atazanavir and PPIs is not recommended. Co-administration of atazanavir with PPIs is expected to substantially decrease atazanavir plasma concentrations and thereby reduce its therapeutic effect.

Co-administration of PPIs in healthy subjects and in transplant patients receiving MMF has been reported to reduce the exposure to the active metabolite, mycophenolic acid (MPA), possibly due to a decrease in MMF solubility at an increased gastric pH. The clinical relevance of reduced MPA exposure on organ rejection has not been established in transplant patients receiving PPIs and MMF. Use rabeprazole with caution in transplant patients receiving MMF.

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.

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.

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 Fertility, pregnancy and lactation

Pregnancy

There are no data on the safety of rabeprazole in human pregnancy. Reproduction studies performed in rats and rabbits have revealed no evidence of impaired fertility or harm to the foetus due to rabeprazole sodium, although low foeto-placental transfer occurs in rats. Rabeprazole is contraindicated during pregnancy.

Breastfeeding

It is not known whether rabeprazole sodium is excreted in human breast milk. No studies in lactating women have been performed. Rabeprazole sodium is however excreted in rat mammary secretions. Therefore, Rabeprazole must not be used during breast feeding.

4.7 Effects on ability to drive and use machines

Based on the pharmacodynamic properties and the adverse events profile, it is unlikely that Rabeprazole 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 Class	Common	Uncommon	Rare	Very Rare	Not known
Infections and infestations	Infection				
Blood and lymphatic system disorders			Neutropenia Leucopenia Thrombocytopenia Leucocytosis		
Immune system disorders			Hypersensitivity		
Metabolism and nutrition disorders			Anorexia		Hyponatremia Hypomagnesaemia
Psychiatric disorders	Insomnia	Nervousness	Depression		Confusion
Nervous system disorders	Headache Dizziness	Somnolence			
Eye disorders			Visual disturbance		
Vascular disorders					Peripheral oedema
Respiratory, thoracic and mediastinal disorders	Cough Pharyngitis Rhinitis	Bronchitis Sinusitis			
Gastrointestinal disorders	Diarrhoea Vomiting Nausea Abdominal pain Constipation Flatulence Fundic gland	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-Johnson syndrome (SJS)	Subacute cutaneous lupus erythematosus
Musculoskeletal and connective tissue disorders	Non-specific pain Back pain	Myalgia Leg cramps Arthralgia Fracture of the hip,wrist or spine			
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		

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 benzimidazole 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

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5.3 Pharmacokinetic properties

Absorption

Absolute bioavailability Rabeprazole I.V. is 100 %.

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 14C-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.

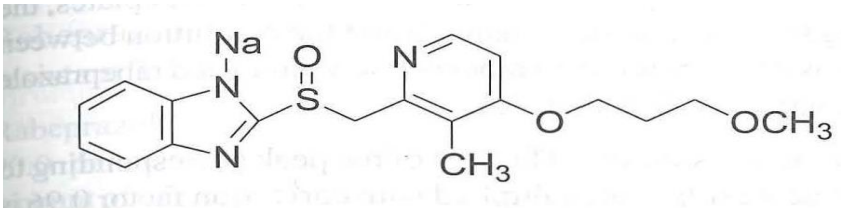
6. Nonclinical properties Description

Non-clinical effects were observed only at exposures sufficiently in excess of the maximum human exposure that make concerns for human safety negligible in respect of animal data.

Studies on mutagenicity gave equivocal results. Tests in mouse lymphoma cell line were positive, but in vivo micronucleus and in vivo and in vitro DNA repair tests were negative. Carcinogenicity studies revealed no special hazard for humans.

7. Description

Rabeprazole sodium is 2-({[4-(3-methoxypropoxy)-3-methyl- 2-pyridinyl]methyl} sulphinyl)-lH-benzimidazole sodium having molecular formula of C18H20N3O3S,Na molecular weight is 381.4. The chemical structure is:



Rabeprazole is a white to light yellow, crystalline powder, hygroscopic. It is soluble in water.

Product Description:
VELOZ INJCTION
Flint glass vial with Red flip off lacquered Aluminium seal and grey butyl rubber stopper containing white to off-white cake or powder.

8. Pharmaceutical particulars

8.1 Incompatibilities
None stated.

8.2 Shelf-life
Do not use later than the date of expiry.

8.3 Packaging information
VELOZ inj available 20 mg per vial.
For I.V. use only after reconstitution. Keep all medicines out of reach children.
The reconstituted injection should not be used if it contains visible particulate matter.

8.4 Storage and handing instructions
STORE BELOW 25º C, PROTECTED FROM LIGHT AND MOISTURE.

9. Patient counselling information

Package leaflet: information for the patient

VELOZ INJECTION

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.

What is in this leaflet?

9.1 What Veloz Injection is and what it is used for

VELOZ inj 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.

VELOZ inj is used to treat the following conditions:

- For the short-term treatment of gastric and duodenal ulcer, Gastroesophageal reflux Disease (GERD) as an alternative to oral therapy in patients who are unable to take oral proton pump inhibitors.

9.2 What you need to know before you take Veloz Inj

Do not take Veloz Injection if:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking VELOZ inj 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 inj 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 inj 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 inj. 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 inj.

Children

VELOZ inj 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 inj and see a doctor straight away.

Taking a proton pump inhibitor like VELOZ inj, 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 inj

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 inj 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 inj 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 inj treatment.

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

Pregnancy, breast feeding and fertility

- Do not use VELOZ inj if you are pregnant or think you may be pregnant
- Do not use VELOZ inj 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 inj. If this happens, do not drive or use any tools or machines.

9.3 How to take Veloz Injection

Always take this medicine exactly as directed by the Physician.

Veloz injection should be reconstituted with 5 ml of Sterile Water for Injection IP (provided with this pack) and administered as IV Bolus slowly over a period of 15 minutes. For Intravenous infusion, Veloz injection should be reconstituted with 5ml of Sterile Water for Injection I.P. and

further diluted with 100 ml of 0.9% Sodium Chloride Injection I.P. or 5% Dextrose Injection I.P. or compound sodium lactate injection I.P. to a final concentration of approximately 0.2 mg/ ml.

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 inj 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)

- 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)"
- Rash, possibly with pain in the joints

If you are on VELOZ inj 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 to perform 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. 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: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

9.5 How to store Veloz Injection

Store below 25º C, protected from light and moisture.

Reconstituted injection is to be used within 24 hr.

9.6 Contents of the pack and other information

Each carton contains:
(A) Each vial contains Rabeprazole sodium I.P. 20 mg (As lyophilized Powder)
(B) Each ampoule contains: Sterile water for Injecton IP q.s. to 5 ml

10. Details of manufacturer

Torrent Pharmaceuticals Ltd
Indrad-382 721,Dist.Mehsana, INDIA.
At:G-17/1,MIDC,
Tarapur Industrial Area,
Boisar, Dist.Thane-401 506.

11. Details of permission or licence number with date

KD-1832 A issued on 03.12.2004

12. Date of revision

Mar/2020

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/VELOZ INJ/20 mg/Mar-20/03/PI