EUREPA-V

To be sold by retail on the prescription of a R.M.P only.

Abbreviated Prescribing information for EUREPA-V (Repaglinide and Voglibose Tablets)

[Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Repaglinide lowers the blood glucose levels acutely by stimulating the release of insulin from the pancreas, an effect dependent upon functioning β -cells in the pancreatic islets. Repaglinide closes ATP-dependent potassium channels in the β -cell membrane via a target protein different from other secretagogues. This depolarises the β -cell and leads to an opening of the calcium channels. The resulting increased calcium influx induces insulin secretion from the β -cell. Voglibose is an alpha glucosidase inhibitor which reduces intestinal absorption of starch, dextrin, and disaccharides by inhibiting the action of aglucosidase in the intestinal brush border. Inhibition of this enzyme catalyzes the decomposition of disaccharides into monosaccharides and slows the digestion and absorption of carbohydrates.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician.

CONTRAINDICATION: Hypersensitivity to active substances or to any of the excipients of this product, Diabetes mellitus type 1, C-peptide negative, Diabetic ketoacidosis, with or without coma, Severe hepatic function disorder, Concomitant use of gemfibrozil, Severe infection, before and after operation or with serious trauma, Gastrointestinal obstruction or predisposition to it.

WARNINGS & PRECAUTIONS: Eurepa-V should be limited to patients who have established diabetes, Hypoglycaemia, Combination with insulin secretagogues, with Neutral Protamine Hagedorn (NPH) insulin or thiazolidinediones, with metformin, Acute coronary syndrome, Repaglinide should be used with caution in patients receiving medicinal products which influence Repaglinide and Voglibose metabolism, Patients with history of laparotomy or ileus, with chronic intestinal disease accompanied by disturbance in digestion and absorption, with aggravating symptoms due to increased generation of intestinal gas (eg, roemheld syndrome, severe hernia, and stenosis and ulcer of the large intestine), with serious hepatic or renal disorders.

DRUG INTERACTION: The following substances may enhance and/or prolong the hypoglycaemic effect of Repaglinide: Gemfibrozil, clarithromycin, itraconazole, ketokonazole, trimethoprim, ciclosporin, deferasirox, clopidogrel, other antidiabetic substances, monoamine oxidase inhibitors (MAOI), non selective beta blocking substances, angiotensin converting enzyme (ACE)-inhibitors, salicylates, NSAIDs, octreotide, alcohol, and anabolic steroids, gemfibrozil, trimethoprim, itraconazole, clarithromycin, *clopidogrel*. Oral contraceptives, rifampicin, barbiturates, carbamazepine, thiazides, corticosteroids, danazol, thyroid hormones and sympathomimetics. When Voglibose is administered concomitantly with drugs that enhance or diminish the hypoglycemic action of antidiabetic drugs, caution should be taken. Examples of drugs enhancing the hypoglycemic action of antidiabetic drugs: ablockers, salicylic acid preparations, monoamine oxidase inhibitors, and fibrate derivatives.

Examples of drugs diminishing the hypoglycemic action of antidiabetic drugs: epinephrine, adrenocortical hormone, and thyroid hormone.

ADVERSE REACTIONS: Allergic reactions, Face oedema, Hypoglycaemia, Hypoglycaemic coma and hypoglycaemic unconsciousness, hyperkalemia, Refraction disorder, blurred vision, Cardiovascular disease, Abdominal pain, diarrhoea, Vomiting, constipation, Nausea, loose stools, anorexia, heartburn, abdominal distension, increased flatus, intestinal obstruction, Abnormal hepatic function, increased liver enzymes, hyperammonemia, Hypersensitivity, diaphoresis, alopecia, Anemia; thrombocytopenia, and leucopenia, Headache, Numbness, Hot Flushes, malaise, weakness, Hyperammonemia, Abdominal discomfort, Abdominal distension, Abdominal pain upper, Gastritis, Hyperchlorhydria, Asthenia, Fatigue, Oedema peripheral, Peripheral swelling, Pyrexia, Swelling face, Furuncle,

Pharyngitis, Sinusitis, Upper respiratory tract infection, Viral infection, Decreased appetite, Hypertriglyceridaemia, Fibromyalgia, Musculoskeletal pain, Periarthritis, Diabetic neuropathy, Cough, Oropharyngeal pain, Hyperhidrosis, Dizziness.



IN/EUREPA-V 0.5+0.2, 0.5+0.3, 1+0.2, 1+0.3/MAR-2021/01/ABPI (Additional information is available on request)