VOGLITOR R

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only. Abbreviated Prescribing information for VOGLITOR R (Repaglinide and Voglibose Tablets I.P)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Repaglinide Repaglinide is a short-acting oral secretagogue. 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** Voglibose is an alpha glucosidase inhibitor which reduces intestinal absorption of starch, dextrin, and disaccharides by inhibiting the action of α-glucosidase in the intestinal brush border. Inhibition of this enzyme catalyzes the decomposition of disaccharides into monosaccharides and slows the digestion and absorption of carbohydrates; the postprandial rise in plasma glucose is blunted in both normal and diabetic subjects resulting in improvement of post prandial hyperglycemia and various disorders caused by hyperglycemia. α-Glucosidase inhibitors do not stimulate insulin release and therefore do not result in hypoglycemia.

INDICATION: It is indicated For the treatment of Type 2 Diabetes Mellitus as an adjunct to diet and exercise to improve glycemic control.

DOSAGE AND ADMINISTRATION: Dose: As directed by the Physician.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients, Diabetes mellitus type 1, C-peptide negative, Severe hepatic function disorder, Concomitant use of gemfibrozil, Diabetic ketoacidosis, with or without coma.

WARNINGS & PRECAUTIONS: <u>Hypoglycaemia</u> - Repaglinide, like other insulin secretagogues, is capable of producing hypoglycaemia. Though the frequency of hypoglycaemia reported with Voglitor R combination was less than that reported with Repaglinide alone, <u>Combination with insulin secretagogues</u> - The blood glucose-lowering effect of oral hypoglycaemic medicinal products decreases in many patients over time, <u>Combination with Neutral Protamine Hagedorn (NPH) insulin or thiazolidinediones</u> - As per reported data, trials of combination therapy with NPH insulin or thiazolidinediones have been performed. However, the benefit risk profile remains to be established when comparing to other combination therapies, <u>Combination with metformin</u> - Combination treatment with metformin is associated with an increased risk of hypoglycaemia, <u>Acute coronary syndrome</u> - The use of Repaglinide might be associated with an increased incidence of acute coronary syndrome.

DRUG INTERACTION: 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, α -blockers, salicylic acid preparations, monoamine oxidase inhibitors, and fibrate derivatives.

ADVERSE REACTIONS: Allergic reactions, Hypoglycaemic coma and hypoglycaemic unconsciousness, hyperkalemia, Refraction disorder, blurred vision, Cardiovascular disease, Nausea, loose stools, Abnormal hepatic function, Hypersensitivity, Anemia; thrombocytopenia, and leucopenia, Hot Flushes, malaise, weakness.

MANUFACTURED BY:



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IN/ VOGLITOR R 0.5+0.2, 0.5+0.3, 1+0.2, 1+0.3/DEC-2023/01/ABPI

(Additional information is available on request)