EUREPA

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

Abbreviated Prescribing information for EUREPA (Repaglinide Tablets 0.25mg, 0.5mg, 1mg and 2mg I.P**)**

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: 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.

DOSAGE AND ADMINISTRATION: As directed by physician.

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

WARNINGS & PRECAUTIONS: Repaglinide should only be prescribed if poor blood glucose control and symptoms of diabetes persist despite adequate attempts at dieting, exercise and weight reduction, Hypoglycaemia: Repaglinide, like other insulin secretagogues, is capable of producing hypoglycaemia, Combination with insulin secretagogues, Combination with metformin, Combination treatment with metformin is associated with an increased risk of hypoglycaemia, Acute coronary syndrome, Repaglinide should be used with caution or be avoided in patients receiving medicinal products which influence repaglinide metabolism. If concomitant use is necessary, careful monitoring of blood glucose and close clinical monitoring should be performed.

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, Co-administration of gemfibrozil (600 mg twice daily), an inhibitor of CYP2C8, and repaglinide (a single dose of 0.25 mg) increased the repaglinide AUC 8.1-fold and Cmax 2.4 fold in healthy volunteers, Rifampicin, a potent inducer of CYP3A4, but also CYP2C8, acts both as an inducer and inhibitor of the metabolism of repaglinide, Co-administration of 200 mg ketoconazole increased the repaglinide (AUC and Cmax) by 1.2-fold with profiles of blood glucose concentrations altered by less than 8% when administered concomitantly (a single dose of 4 mg repaglinide), β-blocking medicinal products may mask the symptoms of hypoglycaemia. Co-administration of cimetidine, nifedipine, oestrogen, or simvastatin with repaglinide, all CYP3A4 substrates, did not significantly alter the pharmacokinetic parameters of repaglinide. The following substances may reduce the hypoglycaemic effect of repaglinide: Oral contraceptives, rifampicin, barbiturates, carbamazepine, thiazides, corticosteroids, danazol, thyroid hormones and sympathomimetics. No interaction studies have been performed in children and adolescents.

ADVERSE REACTIONS: Hypoglycaemia, Allergy, Stomach pain, Diarrhoea, Acute coronary syndrome (but it may not be due to the medicine), Vomiting, Constipation, Visual disturbances, Severe liver problems, abnormal liver function, increased liver enzymes in your blood, hypersensitivity (such as rash, itchy skin, redening of the skin, swelling of the skin), feeling sick (nausea).

Manufactured by:
Torrent Pharmaceutical Ltd,
32 No Middle Camp, NH-10, East District,
Gangtok, Sikkim-737 135.

IN/ EUREPA 0.25, 0.5, 1,2mg /APR-21/03/ABPI

(Additional information is available on request)