IMEXTOR SR

To be sold by retail only under the prescription of Endocrinologists or Internal Medicine Specialists only

Abbreviated Prescribing information for IMEXTOR SR (Imeglimin Hydrochloride Sustained Release Tablets 500 mg/1000 mg)

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Imeglimin's mechanism of action involves dual effects: (a) amplification of glucose-stimulated insulin secretion (GSIS) and preservation of β-cell mass; and (b) enhanced insulin action, including the potential for inhibition of hepatic glucose output and improvement in insulin signalling in both liver and skeletal muscle. At a cellular and molecular level, Imeglimin's underlying mechanism may involve correction of mitochondrial dysfunction, a common underlying element of T2D pathogenesis. Overall, Imeglimin appears to target a key root cause of T2D: defective cellular energy metabolism. This potential mode of action is unique and has been shown to differ from that of other major therapeutic classes, including biguanides, sulphonylureas and glucagon-like peptide-1 receptor agonists.

INDICATIONS: It is indicated for the treatment of type 2 diabetes mellitus inadequately controlled with diet and exercise alone.

DOSAGE AND ADMINISTRATION: Take Imeglimin SR orally once daily with a post-meal. Patients taking two Imeglimin SR tablets should take the tablets together.

Individualize the dosage of Imeglimin SR on the basis of the patient's current regimen, effectiveness, and tolerability.

The maximum recommended dose of Imeglimin is 2000 mg per day.

For patients taking Imeglimin HCL immediate release 500 mg twice daily, the recommended equivalent dose of Imeglimin SR is one tablet of 1000 mg once daily.

For patients taking imeglimin HCL immediate release 1000 mg twice daily, the recommended equivalent dose of Imeglimin SR is two tablets of 1000 mg, once daily taken together.

If you miss a dose of Imeglimin Tablets, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular schedule. Do not double the dose.

CONTRAINDICATION: Patients with a history of hypersensitivity to the ingredients of this drug. Patients with severe ketosis, diabetic coma or precoma, type 1 diabetes [Infusion, prompt correction of hyperglycemia with insulin is essential.]. Patients with severe infections, before and after surgery, and with serious trauma. [Because glycemic control by insulin injection is desired, administration of this drug is not suitable.]

WARNINGS & PRECAUTIONS: The application of this drug should be considered only when the effect is insufficient after sufficient diet and exercise therapy, which are the basics of diabetes treatment. Patients with renal dysfunction, it is recommended to perform renal function check regularly, as the excretion of this drug may be delayed and the blood concentration of this drug may increase. If hypoglycemic symptoms (initial symptoms: weakness, severe hunger, sweating, etc.) are observed, take appropriate measures such as ingesting food containing carbohydrates.

DRUG INTERACTIONS: This drug is mainly excreted as unchanged drug from the kidney. Be aware of the development of hypoglycemia. In particular, when used in combination with insulin preparations, sulfonylureas or fast acting insulin secretagogues, the risk of hypoglycemia may increase. To reduce the risk of hypoglycemia caused by these drugs, consider reducing the dose of insulin preparations, sulfonylureas, or fast acting insulin secretagogues. Be aware of the development of hypoglycemia and gastrointestinal symptoms with Biguanide drugs. Administer while carefully observing blood glucose level and other patient conditions in Drugs that enhance the hypoglycemic effect i.e. β-blockers, Salicylic acid

agents, Monoamine oxidase inhibitors, etc and Drugs that reduce hypoglycemic effects i.e. Adrenaline, adrenocortical hormone thyroid hormone, etc.

ADVERSE REACTIONS: Hypoglycemia, Nausea, Diarrhea, Constipation, Cystitis, Loss Of Appetite, Diabetic Retinopathy, Diabetic Retinal Edema / Macular Edema, Vomiting, Abdominal Discomfort, Dyspepsia, Upper Abdominal Pain, Loose Stools, Abdominal Distension, Gastroesophageal Reflux Disease, Increased Blood Lactate, Increased Lipase and Weight Loss etc.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/ IMEXTOR SR (500/1000) /JUN-24/01/ ABPI

(Additional information is available on request)