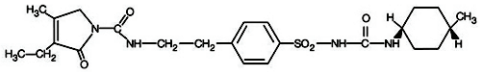
SPANBEC®

स्पानबेक

(Glimepiride)

DESCRIPTION:

SPANBEC is an oral sulfonylurea that contains the active ingredient glimepiride. Glimepiride molecular weight of 490.62. It is a white to yellowish-white, crystalline, odorless to practically odorless powder and is practically insoluble in water. The structural formula is:



CLINICAL PHARMACOLOGY:

Mechanism of Action:

Glimepiride primarily lowers blood glucose by stimulating the release of insulin from pancreatic beta cells. Sulfonylureas bind to the sulfonylurea receptor in the pancreatic beta-cell plasma membrane, leading to closure of the ATP-sensitive potassium channel, thereby stimulating the release of insulin.

Pharmacodynamics:

In healthy subjects, the time to reach maximal effect (minimum blood glucose concentrations) was approximately 2-3 hours after single oral doses of SPANBEC. The effects of SPANBEC on HbA1c, fasting plasma glucose, and post-prandial glucose have been assessed in clinical trials.

Pharmacokinetics:

Absorption

Studies with single oral doses of glimepiride in healthy subjects and with multiple oral doses in patients with type 2 diabetes showed peak drug concentrations (Cmax) 2 to 3 hours post-dose. When glimepiride was given with meals, the mean Cmax and AUC (area under the curve) were decreased by 8% and 9%, respectively.

Distribution

After intravenous dosing in healthy subjects, the volume of distribution (Vd) was 8.8 L (113 mL/kg), and the total body clearance (CL) was 47.8 mL/min. Protein binding was greater than 99.5%.

Metabolism

Glimepiride is completely metabolized by oxidative biotransformation after either an intravenous or oral dose. The major metabolites are the cyclohexylhydroxy methyl derivative (M1) and the carboxyl derivative (M2). Cytochrome P450 2C9 is involved in the biotransformation of glimepiride to M1. M1 is further metabolized to M2 by one or several cytosolic enzymes. M2 is inactive. In animals, M1 possesses about one-third of the pharmacological activity of glimepiride, but it is unclear whether M1 results in clinically meaningful effects on blood glucose in humans.

Excretion

Approximately 60% of the total radioactivity was recovered in the urine in 7 days. M1 and M2 accounted for 80-90% of the radioactivity recovered in the urine. Approximately 40% of the total radioactivity was recovered in feces. M1 and M2 accounted for about 70% (ratio of M1 to M2 was 1:3) of the radioactivity recovered in feces. No parent drug was recovered from urine or feces.

Geriatric Patients

The mean AUC at steady state for the older patients was approximately 13% lower than that for the younger patients; the mean weight-adjusted clearance for the older patients was approximately 11% higher than that for the younger patients.

Gender

There were no differences between males and females in the pharmacokinetics of glimepiride when adjustment was made for differences in body weight.

INDICATIONS:

SPANBEC is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Important Limitations of Use:

SPANBEC should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis, as it would not be effective in these settings.

DOSAGE & ADMINISTRATION:

Recommended Dosing

SPANBEC should be administered with breakfast or the first main meal of the day. The recommended starting dose of SPANBEC is 1 mg or 2 mg once daily. Patients at increased risk for hypoglycemia (e.g., the elderly or patients with renal impairment) should be started on 1 mg once daily.

After reaching a daily dose of 2 mg, further dose increases can be made in increments of 1 mg or 2 mg based upon the patient's glycemic response. Up-titration should not occur more frequently than every 1-2 weeks. A conservative titration scheme is recommended for patients at increased risk for hypoglycemia. The maximum recommended dose is 8 mg once daily.

Patients being transferred to SPANBEC from longer half-life sulfonylureas (e.g., chlorpropamide) may have overlapping drug effect for 1-2 weeks and should be appropriately monitored for hypoglycemia.

ADVERSE DRUG REACTIONS:

In clinical trials, the most common adverse reactions with SPANBEC were hypoglycemia, dizziness, asthenia, headache, and nausea.

CONTRAINDICATIONS:

SPANBEC is contraindicated in patients with a history of a hypersensitivity reaction to:

- Glimepiride or any of the product's ingredients.
- Sulfonamide derivatives: Patients who have developed an allergic reaction to sulfonamide derivatives may develop an allergic reaction to SPANBEC. Do not use SPANBEC in patients who have a history of an allergic reaction to sulfonamide derivatives.

Reported hypersensitivity reactions include cutaneous eruptions with or without pruritus as well as more serious reactions (e.g. anaphylaxis, angioedema, Stevens-Johnson Syndrome, dyspnea).

DRUG INTERACTIONS:

Drugs that potentiate the hypoglycemic action:

NSAID drugs and other drugs such as Salicylates, Sulfonamides, Chlorphenicol, Coumarins,
Probenicid, Monoamine oxidase inhibitors, and Beta Adrenergic blocking agents.

Drugs that decrease the hypoglycemic Action:

The thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens,
oral contraceptives, phenytoin, nicotinic acid, sympathomimetic, and isoniazid.

Other drugs that Glimepiride interact:

Warfarin, ACE inhibitors, Azole(antifungals), Calcium channel blockers, estrogens, fibrates, HMG-CoA reductase inhibitors, sulfonamides, or thyroid hormones.

SPECIAL PRECAUTIONS:

Care is to be taken while using drug in hepatic/renal/cardiac impairment. There is risk of hypoglycemia in the initial treatment. So, it requires careful monitoring of glucose levels in blood and urine regularly.

OVERDOSE:

An overdosage of SPANBEC, as with other sulfonylureas, can produce severe hypoglycemia. Mild episodes of hypoglycemia can be treated with oral glucose. Severe hypoglycemic reactions constitute medical emergencies requiring immediate treatment. Severe hypoglycemia with coma, seizure, or neurological impairment can be treated with glucagon or intravenous glucose. Continued observation and additional carbohydrate intake may be necessary because hypoglycemia may recur after apparent clinical recovery.

PRESENTATION:

SPANBEC-1:

- Each tablet contains: Glimepiride1 mg.
  Packaging:30 Tablets X 5Blisters

SPANBEC-2:

- Each tablet contains: Glimepiride 2 mg.
  Packaging: 30 Tablets X 5 Blisters

SPANBEC-3:

- Each tablet contains: Glimepiride 3 mg.
  Packaging: 30 Tablets X 5 Blisters

SPANBEC-4:

- Each tablet contains: Glimepiride 4 mg.
  Packaging: 20 Tablets X 5 Blisters

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Manufactured by:
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