SWIBETIC®

Glipizide and Metformin Hydrochloride

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Composition:
Each **Swibetic®** Tablet contains
Glipizide 2.5mg
Metformin Hydrochloride 500mg

Properties
Swibetic® contains two oral antihyperglycemic drugs used in the management of type 2 diabetes, Glipizide and Metformin hydrochloride. Glipizide appears to lower blood glucose acutely by stimulating the release of insulin from the pancreas, an effect dependent upon functioning beta cells in the pancreatic islets. Extra pancreatic effects may play a part in the mechanism of action of oral sulfonylurea hypoglycemic drugs. Metformin hydrochloride decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

Pharmacokinetics
Gastrointestinal absorption of Glipizide is uniform, rapid, and essentially complete. Peak plasma concentrations occur 1 to 3 hours after a single oral dose. Glipizide does not accumulate in plasma on repeated oral administration. The absolute bioavailability of a 500 mg Metformin hydrochloride tablet given under fasting conditions is approximately 50% to 60%. Food decreases the extent of and slightly delays the absorption of Metformin; the metabolism of Glipizide is extensive and occurs mainly in the liver. The elimination half-life ranges from 2 to 4 hours in normal subjects, Metformin is excreted unchanged in the urine, approximately 90% of the absorbed drug is eliminated within the first 24 hours, with a plasma elimination half-life of approximately 6.2 hours.

Indications and usage
Swibetic® is indicated as initial therapy, as an adjunct to diet and exercise, to improve glycemic control in patients with type 2 diabetes whose hyperglycemia cannot be managed with diet and exercise alone. It is also indicated as second-line therapy when diet, exercise, and initial treatment with a sulfonylurea or Metformin do not result in adequate glycemic control.

Contraindications
- Renal disease or renal dysfunction
- Known hypersensitivity to Glipizide or Metformin hydrochloride.
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.

Warnings / Precautions
Lactic acidosis is a rare, but serious metabolic complication that can occur due to Metformin accumulation during treatment with **Swibetic®**; when it occurs, it is fatal in approximately 50% of cases. Reported cases have occurred primarily in diabetic patients with significant renal insufficiency. The **Swibetic®** treatment should not be initiated in patients ≥80 years of age unless measurement of creatinine clearance demonstrates that renal function is not reduced. **Swibetic®** should be promptly withheld in the presence of any condition associated with hypoxemia, dehydration, or sepsis. **Swibetic®** should generally be avoided in patients with clinical or laboratory evidence of hepatic disease. Patients should be cautioned against excessive alcohol intake, either acute or chronic, when taking **Swibetic®**, since alcohol potentiates the effects of Metformin hydrochloride on lactate metabolism. In addition, **Swibetic®** should be temporarily discontinued prior to any intravascular radiocontrast study and for any surgical procedure.

Pregnancy & Lactation
Swibetic® should not be used during pregnancy unless clearly needed. There are no adequate and well-controlled studies in pregnant women with **Swibetic®** or its individual components. Some sulfonylurea drugs are known to be excreted in human milk. Because the potential for hypoglycemia in nursing infants may exist, a decision should be made whether to discontinue nursing or to discontinue **Swibetic®**, taking into account the importance of the drug to the mother. If **Swibetic®** is discontinued, and if diet alone is inadequate for controlling blood glucose, insulin therapy should be considered.

Pediatric Use
Safety and effectiveness of **Swibetic®** in pediatric patients have not been established.

Adverse Reactions
The most common clinical adverse events are Upper respiratory infection, Diarrhea, Dizziness, Hypertension, Nausea/vomiting.

Over dosage
Over dosage of sulfonylureas, including Glipizide can produce hypoglycemia. Mild Hypoglycemic symptoms, without loss of consciousness or neurological findings, should be treated aggressively with oral glucose and adjustments in drug dosage and/or meal patterns. If hypoglycemic coma is diagnosed or suspected, the patient should be given a rapid intravenous injection of concentrated (50%) glucose solution. This should be followed by a continuous infusion of a more dilute (10%)

glucose solution. Clearance of Glipizide from plasma would be prolonged in persons with liver disease. Because of the extensive protein binding of Glipizide, dialysis is unlikely to be of benefit.

Lactic acidosis has been reported in approximately 32% of Metformin overdose cases. Metformin is dialyzable with a clearance of up to 170 ml/min under good haemodynamic conditions. Therefore, hemodialysis may be useful for removal of accumulated drug from patients in whom Metformin over dosage is suspected.

Dosage and Administration

Dosage of **Swibetic®** must be individualized on the basis of both effectiveness and tolerance while not exceeding the maximum recommended daily dose of 20 mg Glipizide / 2000 mg Metformin**.** For patients with type 2 diabetes whose hyperglycemia cannot be satisfactorily managed with diet and exercise alone, the recommended starting dose is 2.5mg/500 mg once a day with a meal. Dosage increases to achieve adequate glycemic control should be made in increments of one tablet per day every two weeks up to maximum of 10mg / 1000mg or 10mg / 2000mg **Swibetic®.** For patients not adequately controlled on either Glipizide (or another sulfonylurea) or Metformin alone, the recommended starting dose of **Swibetic®** is 2.5mg/500mg or 5mg/500mg twice daily with the morning and evening meals. The daily dose should be titrated in increments of no more than 5 mg/500 mg from the minimum effective dose to achieve adequate control of blood glucose or to a maximum dose of 20 mg / 2000 mg per day.

Presentation

Swibetic® is available in packs of 3x10 and 10x10 Tablets

Storage

Store below 30°C

KEEP OUT OF THE REACH OF CHILDREN: Parents and caregivers are advised to oversee treatment in children.

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Manufactured by:
Vapi Care Pvt. Ltd. India.
For: swiss pharma nigeria Ltd.,
5, Dopemu Road, Agege, Lagos.
Under licence of Global Healthcare Ltd.,
Switzerland.

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