MedChoice
Endocrine

Metformin HCl

Gludin

500 mg • 850 mg Film-Coated Tablet

ORAL HYPOGLYCEMIC

PRODUCT DESCRIPTION:
Metformin Hydrochloride 500 mg Film-coated Tablet (Gludin) is a white, round biconvex, film-coated tablet.
Metformin Hydrochloride 850 mg Film-coated Tablet (Gludin) is a white, capsule-shaped, biconvex film-coated tablet, plain on one side and scored on the other side.

FORMULATION:
Each Film-coated Tablet contains:
Metformin Hydrochloride, BP ..... 500 mg
Metformin Hydrochloride, BP ..... 850 mg

CLINICAL PHARMACOLOGY:
Pharmacodynamics:
Metformin is a biguanide hypoglycemic agent lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and as a result does not produce hypoglycemia.

Pharmacokinetics:
Metformin Hydrochloride (Gludin) is slowly and incompletely absorbed from the gastrointestinal tract. A single 500 mg dose is reported to have a bioavailability of 50-60% (may be reduced in the presence of food). Plasma protein binding is negligible. It is excreted as unchanged drug in the urine. Plasma elimination half-life is reported to range from about 2 to 6 hours after oral administration.

INDICATION:
Metformin Hydrochloride (Gludin) is a biguanide hypoglycemic agent used in the treatment of Non-Insulin-Dependent Diabetes Mellitus. It is given to patients who are no longer responding to sulphonylureas, either alone or in combination with sulphonylurea.

DOSAGE AND ADMINISTRATION:
Adults:
Monotherapy and combination with other oral antidiabetic agents. The usual starting dose is one tablet of Metformin 500 mg or Metformin 850 mg 2 – 3 times daily with or after meals. Metformin must be taken daily without interruption, except if specifically indicated by the doctor. If the patient has forgotten to take Metformin, the next dose should be taken at the usual time. Do not double the dose of Metformin. If the patient has taken more Metformin tablets than indicated, the doctor or pharmacist must be consulted immediately.

After 10 to 15 days, the dose may be slowly increased by an increment of one tablet depending on blood glucose measurements. A slow increase of dose may improve gastrointestinal tolerability. The maximum recommended dose of Metformin is 3 g daily, taken as 3 divided doses.
If transfer from another oral antidiabetic is intended: discontinue the other agent and initiate Metformin at the dose indicated above.

Combination with insulin: Metformin and Insulin may be used in combination therapy to achieve better blood glucose control. Unless otherwise prescribed, Metformin is given at the usual starting dose of one tablet of Metformin 500 mg or Metformin 850 mg 2 – 3 times daily, while Insulin dosage is just adjusted on the basis of blood glucose measurements.

Elderly: Due to the potential for decreased renal function in elderly subjects, the Metformin dosage should be adjusted based on renal function. Regular assessment of renal function is necessary.

Children and adolescents: *Monotherapy and combination with insulin*. Metformin 500 mg tablet can be used in children from 10 years of age and adolescents.
The maximum recommended dose of Metformin is 2 g daily, taken as 2 or 3 divided doses.

PRECAUTIONS AND CONTRAINDICATIONS:
Metformin Hydrochloride (Gludin) should not be used in Insulin-Dependent Diabetes Mellitus. Use in Non-Insulin-Dependent Diabetes Mellitus is contraindicated in patients with ketoacidosis and in those with severe infection, stress, trauma and other severe conditions where it is unlikely to control hyperglycemia.
It should not be given in severe impairment of renal or hepatic function because of an increased risk of hypoglycemia.
It should not be used in patients with heart failure, recent myocardial infarction, dehydration, acute or chronic alcoholism or any other condition likely to predispose to Lactic Acidosis.

WARNING:
Lactic Acidosis is a rare, but serious (high mortality in the absence of prompt treatment), metabolic complication that occurs due to accumulation of Metformin during treatment.

"For suspected adverse drug reaction, report to FDA: *www.fda.gov.ph*.
Seek medical attention immediately at first sign of any adverse drug reaction."

PREGNANCY AND LACTATION:
Metformin Hydrochloride (Gludin) should not be given to pregnant or lactating women since it is excreted in breast milk.

DRUG INTERACTIONS:
Dosage of Metformin Hydrochloride (Gludin) may be lowered in patients receiving Metformin Hydrochloride and Cimetidine to reduce the risk of Lactic Acidosis. Diuretics may increase the risk of Lactic Acidosis due to their potential to decrease renal function. Avoid consumption of alcohol and alcohol-containing medications, as it may cause increase risk of Lactic Acidosis.

ADVERSE DRUG REACTIONS:
Metabolism and Nutrition disorder: Impaired absorption of various substances including Vitamin B12
Nervous system disorders: Taste disturbance
Gastrointestinal disorders: Nausea, Anorexia, Diarrhea
Skin disorders: Pruritus, Erythema, Urticaria

OVERDOSE AND TREATMENT:
Overdosage may lead to Lactic Acidosis. In such cases, medical emergency is required and must be treated in a hospital. The most effective way to remove Lactate and Metformin in the blood is hemodialysis.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

AVAILABILITY:
Metformin Hydrochloride 500 mg Film-coated Tablet ..... Alu-PVC Blister x 10's (Box x 100's)
Registration No.: DRP - 7736
Date of First Authorization: August 2010
Renewal of Authorization: August 2020

Metformin Hydrochloride 850 mg Film-coated Tablet ..... Alu-PVC Blister x 10's (Box x 100's)
Registration No.: DRP - 7737
Date of First Authorization: March 2010
Renewal of Authorization: March 2020

Date of Revision: July 2018

Manufactured for:
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By:
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