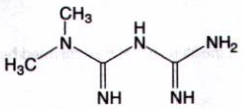
METFORMIN HCl

NEOFORM® 500

500 mg Film-coated Tablet
ORAL HYPOGLYCEMIC



(metformin)

FORMULATION:
Each film-coated tablet contains:
Metformin Hydrochloride, USP ..... 500 mg

DESCRIPTION:
White to off-white, oval, biconvex, film-coated tablet, plain on both sides.

PHARMACOKINETICS:
Metformin hydrochloride is slowly and incompletely absorbed from the gastrointestinal tract; the absolute bioavailability of a single 500 mg dose is reported to be about 50% to 60%, although this is reduced somewhat if taken with food. Once absorbed, protein binding in plasma is negligible; the drug is excreted unchanged in the urine. The plasma half-life is reported to range from 2 to 6 hours after oral dose. Metformin crosses the placenta and is distributed in breast milk in small amount.

INDICATIONS:
Treatment of type 2 diabetes mellitus in adults, particularly in overweight patients. Metformin may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin. Intensive glucose control with metformin as first line therapy in overweight type 2 diabetic patients has been shown to reduce diabetes complications. Impaired Glucose Tolerance (IGT) for patients in whom lifestyle interventions (diet and exercise) have failed.
Treatment of type 2 diabetes mellitus in children and adolescents from 10 years of age and older.

DOSAGE AND ADMINISTRATION:
Adults
Monotherapy and combination with other oral antidiabetic agents:
The usual starting dose is one tablet of metformin 500 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. Or as prescribed by a physician.

If transfer from another oral antidiabetic is intended, discontinue the other agent and initiate metformin at the dose indicated above.

Combination of 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 2 - 3 times daily, while insulin dosage is 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. Unless otherwise prescribed, the usual starting dose is one tablet of 500 mg twice daily, given during meals or after meals. After 10 to 15 days, the dose may be slowly increased by an increment of one tablet depending on the basis of blood glucose measurements. A slow increase of dose may improve gastrointestinal tolerability. The maximum recommended dose of metformin is 2 g daily, taken as 2 to 3 divided doses.

CONTRAINDICATIONS:
Contraindicated in patients with known hypersensitivity to metformin hydrochloride or to any of the excipients, diabetic coma or ketoacidosis, renal insufficiency, acute or chronic disease which may cause tissue hypoxia (such as cardiac failure, myocardial infarction, respiratory insufficiency, shock), impaired liver function and acute alcohol intoxication.

SPECIAL WARNINGS AND PRECAUTIONS:
Lactic Acidosis
Lactic acidosis is a rare, but serious (high mortality in the absence of prompt treatment), metabolic complication that can occur due to metformin accumulation. Reported cases of lactic acidosis in patients on metformin have occured primarily in diabetic patients with significant renal failure. The incidence of lactic acidosis can and should be reduced by assessing also other associated risk factors such as poorly controlled diabetes, ketosis, prolonged fasting, excessive alcohol intake, hepatic insufficiency and any condition associated with hypoxia.

Renal function
As metformin is excreted by the kidney, creatinine clearance (this can be estimated from serum creatinine levels by using the Cockcroft-Gault formula) should be determined before initiating treatment and regularly thereafter:

* at least annually in patients with normal renal function.
* at least two to four times a year in patients with creatinine clearance at the lower limit of normal and in elderly subjects.

Surgery
Metformin must be discontinued 48 hours before elective major surgery. Therapy may be restarted no earlier than 48 hours following surgery or resumption of oral nutrition and only if normal renal function has been established.

Children and Adolescents
The diagnosis of type 2 diabetes mellitus should be confirmed before treatment with metformin is initiated.

Other Precautions
Avoid consumption of alcoholic beverages.
Patients have to inform their doctor of any other treatment they are receiving and of any infectious diseases such as influenza, respiratory tract infection or urinary tract infection.
All patients should continue their diet with a regular distribution of carbohydrate intake during the day.
Overweight patients should continue their energy restricted diet.
The usual laboratory tests for diabetes monitoring should be performed regularly.
Metformin alone does not cause hypoglycemia, but caution is advised when it is used in combination with insulin or other oral antidiabetics (e.g. sulfonylureas or meglitinides).

DRUG INTERACTIONS:
Use of Metformin hydrochloride with other drugs that lower blood glucose concentrations increases the risk of hypoglycemia, while drugs that increase blood glucose may reduce the effect of metformin hydrochloride therapy.

Alcohol may increase the risk of lactic acidosis as well as of hypoglycemia. Care should be taken if metformin hydrochloride is given with drugs that may impair renal function.

PREGNANCY AND LACTATION:
Uncontrolled diabetes during pregnancy (gestational permanent) is associated with increased risk of congenital abnormalities and perinatal mortality.

Metformin is excreted into human breast milk. No adverse effects were observed in breastfed newborns/infants. However, as only limited data are available, breastfeeding is not recommended during metformin treatment. A decision on whether to discontinue breastfeeding should be made, taking into account the benefit of breastfeeding and the potential risk to adverse effects on the child.

ADVERSE DRUG REACTIONS:
Gastrointestinal disorders such as nausea, vomiting, diarrhea, abdominal pain and loss of appetite may occur. Patients may experience a metallic taste and there may be weight loss. Skin reaction such as erythema, pruritus and urticaria. Lactic acidosis, sometimes fatal, has occurred with metformin hydrochloride. Absorption of various substances including vitamin B_{12} may be impaired.

OVERDOSE AND TREATMENT:
Hypoglycemia has not been seen with metformin doses of up to 85 g, although lactic acidosis has occurred in such circumstances. High overdose of metformin or concomitant risks may lead to lactic acidosis. Lactic acidosis is a medical emergency and must be treated in a hospital. The most effective way to remove lactate and metformin from the blood is hemodialysis.

AVAILABILITY:
500 mg Film-coated Tablet: Alu/ Clear PVDC Blister Pack of 10's (Box of 100's)

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

ADR REPORTING:
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

REGISTRATION NUMBER:
DRP-7406-04

DATE OF FIRST AUTHORIZATION:
22 March 2023

DATE OF REVISION:
March 2023

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

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HIZON LABORATORIES, INC.
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