PATRIOT
Pharmaceuticals Corp.

Metformin HCl

I - max®

500mg Film-Coated Tablet
Oral Hypoglycemic

FORMULATION:
Each tablet contains:
Metformin hydrochloride..... 500 mg

INDICATIONS:
Metformin is a biguanide hypoglycaemia agent used in the treatment of non-insulin dependent diabetes mellitus (NIDDM) not responding to dietary modification.It is used as a monotherapy or in combination with a sulfonylurea product. In Type 1 diabetic patients or insulin deficient patients, who are not adequately controlled, metformin may be combined with insulin.

PHARMACODYNAMICS:
Metformin acts primarily by reducing hepatic glucose production and increasing peripheral glucose uptake. Insulin production is not affected and so hypoglycaemia as a side effect does not occur. Metformin does not cause weight gain and so is the treatment of choice for obese patients. Metformin HCl is equally effective in the non-obese.
It induces comparable effects on fasting plasma glucose (FPG) and glycosylated haemoglobin (HbA) levels to the sulphonylureas. Metformin HCl has a favorable effect on plasma lipids and the homeostatic mechanism.

Metformin HCl does not stimulate insulin release but does require that some insulin be present for it to exert a hypoglycemic effect. Possible mechanisms of action include delay in the absorption of glucose from the gastro-intestinal tract, an increased in insulin sensitivity and inhibition of hepatic gluconeogenesis. Metformin HCl does not usually lower blood-glucose concentrations in non-diabetic subjects.

PHARMACOKINETICS: Metformin hydrochloride is absorbed from the gastro-intestinal tract. It has a plasma half-life of about 3 hours and is not bound to plasma proteins. Metformin HCl is excreted, unchanged, in the urine. Its hypoglycemic action lasts 6-8 hrs.

PRECAUTIONS/INTERACTIONS
Lactic acidosis, a very rare, but serious metabolic complication, most often occurs at acute worsening of renal function or cardiorespiratory illness or sepsis. Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis.
In case of dehydration (severe diarrhoea or vomiting, fever or reduced fluid intake), metformin should be temporarily discontinued and contact with a health care professional is recommended.
Medicinal products that can acutely impair renal function (such as antihypertensives, diuretics and NSAIDs) should be initiated with caution in metformin-treated patients. Other risk factors for lactic acidosis are excessive alcohol intake, hepatic insufficiency, inadequately controlled diabetes, ketosis, prolonged fasting and any conditions associated with hypoxia, as well as concomitant use of medicinal products that may cause lactic acidosis

ADVERSE EFFECT:
Gastrointestinal adverse effects including anorexia, nausea and diarrhea may occur and is dose dependent. These effects can be limited by administering with food and starting with low dose (500 mg once or twice a day), then slowly titrating the dose upwards according to the clinical response.

Patients may experience a metallic taste and there may be weight loss. Absorption of various substances including Vitamm B12 may be impaired. Hypoglycemia is less of a problem with metformin than with the sulphonylureas.

Lactic acidosis is rare and occurs predominantly in patients with renal impairment.

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

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Overdose & Treatment
Hypoglycaemia has not been seen with metformin hydrochloride 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 hospital. The most effective method to remove lactate and metformin is haemodialysis.

CONTRAINDICATIONS:
Metformin HCl is contraindicated in renal impairment and liver failure because of an increased risk of hypoglycemia. Renal impairment may also predispose patients to lactic acidosis. Regular renal and hepatic monitoring is essential.

Metformin HCl should also not be given to patients with heart failure, recent myocardial infarction, dehydration, alcoholism or any other condition likely to predispose to lactic acidosis.

Drug interactions involve drugs also excreted by the renal tubular pathway (e.g. amiloride, cimitidine, digoxin, morphine, procainmide, quinidine, vancomycin, trimethoprim). Cimitidine may increase metformin levels by up to 50%.

Hypersensitivity to metformin or to any of the excipients. Any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis). Diabetic pre-coma. Severe renal failure (GFR < 30 mL/min). Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock. Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock. Hepatic insufficiency, acute alcohol intoxication, alcoholism.

PREGNANCY AND LACTATION:
Use of metformin HCl is not recommended.

DOSAGE AND ADMINISTRATION:
Initial dose of 500 mg three times daily with or after meals, gradually increased if necessary to a maximum of 3 g daily.

AVAILABILITY: Blister Pack x 10's (Box of 60's)

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STORE AT TEMPERATURES NOT EXCEEDING 30°C.

Manufactured for
Patriot Pharmaceuticals Corp.
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