METFORMIN TABLETS 500MG

ACTIVE INGREGIENTS
Metformin Hydrochloride 500mg

EXCIPIENTS
Corn Starch, Lactose 200, Povidone K90, Magnesium Stearate, Isopropyl Alcohol

DOSAGE FORM
Tablets are white, round, flat, 12.0mm in diameter, and scored on one side. The score-line of the tablet is for aesthetic purpose only and the tablet is to be consumed as a whole and not to be broken.

PACK SIZE
PVC/Aluminium Blister Pack 100x10's

GENERAL INDICATIONS
Metformin hydrochloride is a biguanide antidiabetic. It is given orally in the treatment of type 2 diabetes mellitus when dietary management and exercise alone does not result in adequate glycaemic control, and is the drug of first choice in overweight patients.

In adults, metformin tablets may be used as monotherapy or in combination with other oral anti-diabetic agents or with insulin, A reduction of diabetic complications has been shown in overweight type 2 diabetic adult patients treated with metformin as first-line therapy after diet failure.

DOSAGE
Adults with normal renal function
The usual dose is 500mg 3 times daily or 850mg 2 times daily given during or after meals, gradually increased if necessary, at intervals of at least 1 week, to 2 to 3 g daily. Gastrointestinal effects are also common on beginning therapy and it is recommended to start therapy more gradually with 500 mg at breakfast for at least 1 week, then increasing to 500 mg twice daily for at least 1 week, with further increases as required, up to a usual maximum of 2 g daily in 3 divided doses with meals.

Posology on Renal Impairment
A GFR should be assessed before initiation of treatment with metformin containing products and at least annually thereafter. In patients at an increased risk of further progression of renal impairment and in the elderly, renal function should be assessed more frequently, e.g. every 3-6 months.

GFR mL/min	Total maximum daily dose (to be preferably divided into 2-3 daily doses)	Additional considerations
60-89	3000mg	Dose reduction may be considered in relation to declining renal function
45-59	2000mg	Factors that may increase the risk of lactic acidosis should be reviewed before considering initiation of metformin. The starting dose is at most half of the maximum dose.
30-44	1000mg	
<30	-	Metformin is contraindicated

ADVERSE EFFECTS
Common symptoms include anorexia, nausea, vomiting, diarrhoea and taste disturbances. Metallic taste, loss of weight, weakness, and lassitude or skin rashes may occur. In rare cases, lactic acidosis, sometimes fatal, has occurred in patients, in which most were contraindicated and particularly those with renal impairment. Lactic acidosis is heralded by vomiting, abdominal pain, hyperventilation, and diminished consciousness, but occurrence is less common than with other biguanides. Absorption of various substances including vitamin B12 may be impaired. Severe cholestatic hepatitis attributed to metformin has been reported.

DRUG INTERACTIONS
Care should be taken if metformin is given with drugs that may impair renal function. Alcohol also increases the risk of lactic acidosis as well as hypoglycaemia. Use of metformin with other drugs that lower glucose concentrations increase the risk of hypoglycaemia, while drug that increases blood glucose may reduce the effect of metformin therapy. Some specific known drug interactions are listed below:

a) Acetazolamide: This agent may cause an altered requirement of metformin.
b) Calcium channel blockers: These agents may have an intrinsic effect on carbohydrate metabolism.
c) Clonidine: This may mask hypoglycaemia.
d) Corticosteroids: These have intrinsic hyperglycaemic effect.
e) Glucagon: This has hyperglycaemic activity.
f) Guanethidine: This may cause an altered antidiabetic effect of metformin.
g) Monoamine oxidase inhibitors: Concomitant use of these may lead to excessive hypoglycaemia.
h) Oral contraceptives: These impair glucose tolerance.
i) Oxytetracycline: This may enhance the effect of insulin.
j) Salicylates: This may cause the enhancement of the hypoglycaemic effect of metformin.
k) Thiazide Diuretics: These may lead to decreased control with metformin.
l) Thyroid products: These may cause an increase in metformin needed.

CONTRAINDICATIONS
Hypersensitivity to metformin or any component of the formulation; severe renal dysfunction (eGFR <30 mL/minute/1.73 m^2).

SPECIAL WARNINGS

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Metformin hydrochloride is inappropriate for patients with diabetic coma, ketoacidosis, severe infections, trauma, or other severe conditions where metformin hydrochloride is unlikely to control the hyperglycaemia; insulin should be used in such situations. Metformin hydrochloride should not be given to patients with mild renal impairment, as it may predispose them to lactic acidosis. Renal function should be monitored throughout therapy. Dehydration may contribute to renal impairment. Conditions associated with hypoxia, such as acute heart failure, recent myocardial infarction, or shock, may increase the risk of lactic acidosis. Other conditions that may also predispose to lactic acidosis in a patient taking metformin hydrochloride include excessive alcohol intake and hepatic impairment. Alcohol should be avoided by patients being treated with metformin.

Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in metformin accumulation and an increased risk of lactic acidosis. Metformin should be discontinued prior to or at the time of the imaging procedure and not restarted until at least 48 hours after, provided that renal function has been re-evaluated and found to be stable.

PREGNANCY AND LACTATION

Pregnancy

It is recommended that diabetes in pregnant women is not treated with metformin hydrochloride, but insulin be used to maintain blood glucose levels as close to normal as possible, to reduce the risk of malformations of the foetus.

Lactation

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

STORAGE AND CONDITIONS

Store below 30°C in a dry place and away from light. Keep container tightly closed.

MARKET AUTHORISATION NUMBER

[TBC]

DATE OF LAST REVISION

18/12/2019

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