METFORMIN

Metformin Tablets BP 500mg

Composition:
Each Film Coated Tablet Contains:
Metformin Hydrochloride BP.....500 mg
Excipients.....q.s.
Approved Colour Used

Pharmaceutical Form:
Film Coated Tablets.

Therapeutic indications:
Metformin used in the treatment of type 2 diabetes mellitus in adults, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycemic control.
Metformin may be used as monotherapy or in combination with other oral antidiabetic agents,
or with insulin.
A reduction of diabetic complications has been shown in overweight type 2 diabetic patients treated with metformin as first-line therapy after diet failure.

Posology and method of administration:
Posology:
Child 10–17 years (specialist use only): Initially 500 mg once daily, dose to be adjusted according to response at intervals of at least 1 week, maximum daily dose to be given in 2–3 divided doses; maximum 2 g per day.

Adult: Initially 500 mg once daily for at least 1 week, dose to be taken with breakfast, then 500 mg twice daily for at least 1 week, dose to be taken with breakfast and evening meal, then 500 mg 3 times a day, dose to be taken with breakfast, lunch and evening meal; maximum 2 g per day.

Method of administration:
For oral administration only.

Contraindications:
• Hypersensitivity to the active substance or to any of the excipients of the formulation.
• Any type of acute metabolic acidosis (such as lactic acidosis, diabetic kaetoacidosis).
• Severe renal failure (GFR <30 mL/min).

Diabetic pre-coma
• 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) as:
- decompensated cardiac failure
- respiratory failure
- recent myocardial infarction
- shock

• Hepatic insufficiency, acute alcohol intoxication, alcoholism

Warnings and Precautions:
Lactic acidosis:
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.

Administration of iodinated contrast agents:
Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in metformin accumulation and an increased risk of lactic acidosis.

Renal function
Metformin is contraindicated in patients with GFR<30 mL/min and should be temporarily discontinued in the presence of conditions that alter renal function.

Cardiac function
In patients with stable chronic heart failure, metformin may be used with a regular monitoring of cardiac and renal function.
For patients with acute and unstable heart failure, metformin is contraindicated.

Surgery
Metformin must be discontinued at the time of surgery under general, spinal or epidural anesthesia.

Other precautions
All patients should continue their diet with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet.

Drug interactions:
Concomitant use not recommended:
Alcohol:
Alcohol intoxication is associated with an increased risk of lactic acidosis, particularly in cases of fasting, malnutrition or hepatic impairment.

Iodinated contrast agents:
Metformin must 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.

Combinations requiring precautions for use:
Some medicinal products can adversely affect renal function which may increase the risk of lactic acidosis, e.g. NSAIDs, including selective cyclo-oxygenase (COX) II inhibitors, ACE inhibitors, angiotensin II receptor antagonists and diuretics, especially loop diuretics. When starting or using such products in combination with metformin, close monitoring of renal function is necessary.

Medicinal products with intrinsic hyperglycaemic activity as glucocorticoids (systemic or by local route) and sympathomimetics:
More frequent blood glucose monitoring may be required, especially at the beginning of treatment.
If necessary, adjust the metformin dosage during therapy with the other drug and upon its discontinuation.

Pregnancy and Lactation:
Pregnancy:
METFORMIN can be used in pregnancy for both pre-existing and gestational diabetes. Women with gestational diabetes should discontinue treatment after giving birth.

Lactation:
METFORMIN may be used during breast-feeding in women with pre-existing diabetes.

Undesirable effects:
Common or very common: Abdominal pain, appetite decreased, diarrhoea (usually transient), gastrointestinal disorder, nausea, taste altered, vomiting.

Rare or very rare: Hepatitis, lactic acidosis (discontinue), skin reactions, vitamin B12 absorption decreased.

Gastro-intestinal side-effects are initially common with metformin, and may persist in some patients, particularly when very high doses are given. A slow increase in dose may improve tolerability.

Overdose:
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.

Storage:
Store below 30°C in dry place, protect from moisture and light.

Keep the medicine out of reach of children.

Presentation:
14 tablets in a blister pack.
Such 2 blisters are packed in a printed carton along with pack insert.

Manufactured by:

US Pharma®
(INDIA) Private Limited
Pioneering Excellence. Redefining Quality.
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