SPMC

METFORMIN TABLETS BP 500mg

PRESENTATION:
Metformin Tablets BP 500mg;
Packs of 500/1000 tablets and blister packs of 200 tablets (20x10)
Each white, circular bi-convex film coated tablets of 11.5mm diameter with "SPC", "SPMC" or "DHS" letters on one side and score mark on the reverse contains Metformin Hydrochloride BP 500mg.

ACTIONS:
Metformin exerts its effect mainly by decreasing gluconeogenesis and by increasing peripheral Utilization of glucose; since it acts only in the presence of endogenous insulin it is effective only if there are some residual functioning pancreatic islet cells.

INDICATIONS AND DOSE:
Type 2 diabetes mellitus [monotherapy or in combination with other antidiabetic drugs (including insulin)]
By mouth using immediate-release medicines
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

Polycystic ovary syndrome
By mouth using immediate-release medicines
Adult: Initially 500 mg once daily for 1 week, dose to be taken with breakfast, then 500 mg twice daily for 1 week, dose to be taken with breakfast and evening meal, then 1.5–1.7 g daily in 2–3 divided doses

CONTRA-INDICATIONS:
Acute metabolic acidosis (including lactic acidosis and diabetic ketoacidosis

CAUTIONS:
Risk factors for lactic acidosis

CAUTIONS, FURTHER INFORMATION:
Risk factors for lactic acidosis Manufacturer advises caution in chronic stable heart failure (monitor cardiac function), and concomitant use of drugs that can acutely impair renal function; interrupt treatment if dehydration occurs, and avoid in conditions that can acutely worsen renal function, or cause tissue hypoxia.

SIDE 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

SIDE-EFFECTS, FURTHER INFORMATION: 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.

PREGNANCY:
Can be used in pregnancy for both preexisting and gestational diabetes. Women with gestational diabetes should discontinue treatment after giving birth.

BREAST FEEDING:
May be used during breast-feeding in women with pre-existing diabetes.

HEPATIC IMPAIRMENT:
Withdraw if tissue hypoxia likely.

RENAL IMPAIRMENT:
In adults Manufacturer advises avoid if eGFR is less than 30 mL/minute/1.73m2.
In children Manufacturer advises avoid if estimated Glomerular filtration rate is less than 30 mL/minute/1.73m2.
Dose adjustments
In children been advised Consider dose reduction in moderate impairment.
In adults been advised reduce dose in moderate Impairment—consult product literature.

PATIENT AND CARER ADVICE:
Manufacturer advises that patients and their carers should be informed of the risk of lactic acidosis and told to seek immediate medical attention if symptoms such as dyspnoea, muscle cramps, abdominal pain, hypothermia, or asthenia occur. Medicines for Children leaflet: Metformin for diabetes

DRUG INTERACTION :
hiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, oral contraceptives, sympathomimetics, phenytoin, nicotininc acid, Ca channel blockers and isoniazid may produce hyperglycaemia which may lead to loss of glycaemic control. Alogliptin: Increased risk of hypoglycaemia when used in combination with sulfonylureas or insulin. Metformin: Concomitant cationic drugs that interfere with renal tubular transport systems (e.g. ranolazine, vandetanib, dolutegravir, and cimetidine) may increase metformin levels. Increased risk of lactic acidosis with topiramate or other carbonic anhydrase inhibitors (e.g. zonisamide, acetazolamide, dichlorphenamide), ACE inhibitor, angiotensin II receptor antagonists, NSAIDs, loop diuretics. May impair vitamin B12 absorption.
Potentially Fatal: Intravascular admin of iodinated contrast agents may cause renal dysfunction, leading to metformin-induced lactic acidosis. vandetanib, Thrombocyte count depressed when metformin given with ketotifen.

PRESCRIBING AND DISPENSING INFORMATION:
In adults Patients taking up to 2 g daily of the standard release Metformin may start with the same daily dose of metformin modified release; not suitable if dose of standard-release tablets more than 2 g daily.

MONITORING REQUIREMENTS: Determine renal function before treatment and at least annually (at least twice a year in patients with additional risk factors for renal impairment, or if deterioration suspected).

MANUFACTURER ADVISES:
patients and their carers should be informed of the risk of lactic acidosis and told to seek immediate medical attention if symptoms such as dyspnoea, muscle cramps, abdominal pain, hypothermia, or asthenia occur. Medicines for Children leaflet: Metformin for diabetes

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:
Keep tightly closed in a cool dry place. Protect from light. Keep all medicines away from children. Store below 30^0C.

Manufactured by:
State Pharmaceutical Manufacturing Corporation
No.11, Sir John Kotalawala Mawatha,
Kandawala Estate,
Ratmalana, Sri Lanka.