

**Composition:**

Metlife® 500: Each film-coated tablet contains Metformin Hydrochloride BP 500 mg.

Metlife® 850: Each film-coated tablet contains Metformin Hydrochloride BP 850 mg.

System Components and Performance:

Metlife® (Metformin Hydrochloride tablets) are oral antihyperglycemic drugs.

Indications:

Metlife® (Metformin Hydrochloride tablets) are oral antihyperglycemic drugs that is indicated in the following cases:

- Non-Insulin dependant diabetes mellitus (NIDDM) or type 2 diabetes, as an adjunct to diet & exercise to improve glycemic control.
- Insulin dependant diabetes mellitus (IDDM), as adjunct therapy in combination with insulin to patients who are often obese.
- May be used concomitantly with a sulfonylurea or insulin to improve glycemic control in adults.

Dosage and Administration:

Metlife® should be given in divided doses (2-3 times/day) with meals. Metlife® should be started at a low dose, with gradual dose escalation, both to reduce gastrointestinal side effects and to permit identification of the minimum dose required for adequate glycemic control of the patient.

Recommended Dosing Schedule :

Adults: The usual starting dose of Metlife® (Metformin Hydrochloride tablets) is 500 mg twice a day or 850 mg once a day, given with meals. Dosage should be increased in increments of 500 mg weekly or 850 mg every 2 weeks, up to a total of 2000 mg per day, given in divided doses. Patients can also be titrated from 500 mg twice a day to 850 mg twice a day after 2 weeks. For those patients requiring additional glycemic control, Metlife® may be given to a maximum daily dose of 2550 mg per day. Dose above 2000 mg may be better tolerated given three times a day with meals. If higher dose of Metformin are required, Metlife® should be used at total daily doses up to 2550 mg administered in divided daily doses, as described above.

Pediatrics: The usual starting dose of Metlife® is 500 mg twice a day, given with meals. Dosage increases should be made in increments of 500 mg weekly up to a maximum of 2000 mg per day, given in divided doses.

Safety and effectiveness of Metlife® in pediatric patients below 10 years have not been established.

Contraindications:

Hypersensitivity to the drug, renal impairment, diabetic coma and ketoacidosis, chronic renal diseases, cardiac failure & recent myocardial infarction, trauma, dehydration, alcohol dependance, pregnancy, breast feeding etc.

Precautions:

Monitoring renal function regularly is advised in all patients taking Metformin. Therapy should be stopped 2-3 days before surgery and clinical investigations such as intravenous urology,

angiography and reinstated only after control of renal function has been regained. Patients receiving continuous therapy should have an annual estimation of vitamin B₁₂ levels. During concomitant therapy with sulfonylurea, blood glucose should be monitored. Metformin & insulin therapy should be carried out in hospital until the correct ratio of the two drugs has been established.

Side Effects :

Usually well tolerated but minor GI disturbances sometimes occur which can be avoided easily by taking the drug with or after food. Some patients may experience a metallic taste. Lactic acidosis may occur but its incidence is very low (approximately 0.03 cases/1000 patient-year). It may induce malabsorption of vitamin B₁₂ & folic acid.

Drug Interactions:

Cimetidine reduces the renal clearance of Metformin. Alcohol potentiates the antihyperglycemic & hyperlactataemic effect of Metformin. It may enhance the effects of anticoagulants. As such patients receiving the two drugs may need adjustment of the anticoagulant dosage. Nifedipine appears to enhance the absorption of Metformin but Metformin has minimal effects on Nifedipine.

Storage Condition:

Store below 25°C in a dry place

Packaging Quantities:

Metlife® 500 : Box containing 10 x 10 tablets in blister packs.

Metlife® 850 : Box containing 5 x 10 tablets in blister packs.

Keep out of reach of children

Manufactured by:
 **Silva**
Pharmaceuticals Limited
Majidce, Noakhali, Bangladesh