

# Obemet<sup>®</sup>

## Metformin HCl

### Composition:

**Obemet<sup>®</sup>** (Metformin HCl) each film coated tablet contains 500 mg and 850 mg of Metformin Hydrochloride.

### Description:

**Obemet<sup>®</sup>** (Metformin) is a biguanide. This oral hypoglycaemic drug is recommended as first-line therapy for type -2 diabetes. It act primarily by reducing hepatic glucose production through activation of the enzyme AMP-activated protien kinase (AMPK). Minor mechanism of action include impairment of renal gluconeogenesis, slowing of glucose absorption from gastrointestinal tract, with increased glucose to lactate conversion by enterocytes, direct stimulation of glycolysis in tissues, increased glucose removal from blood, and reduction of plasma glucagon levels. The biguanide blood glucose lowering action does not depend on functioning pancreatic beta cells. Patients with type -2 diabetes have considerably less fasting hyperglycaemia as well as lower postprandial hyperglycaemia after biguanides; however hypoglycaemia during biguanide thereby is essentially unknown. These agents are therefore more appropriately termed "euglycaemic agent".

### Indication:

**Obemet<sup>®</sup>** (Metformin) is indicated in type -2 diabetes as monotherapy adjunct to diet and exercise. **Obemet<sup>®</sup>** is also indicated for use in combination therapy with sulfonylureas or insulin when single drug do not result in adequate glycemic control.

### Dosage and administration:

**Adults:** The dosage of metformin is from 500 mg to a maximum of 2550 mg daily, with the lowest effective dose being recommended. A common schedule for fasting hyperglycaemia would be to begin with a single 500 mg tablet at bedtime for a week or more. If this is tolerated without gastrointestinal discomfort and if hyperglycaemia persists, a second 500 mg tablet may be added with evening meal. If further dose increase is required an additional 500 mg tablet can be added to be taken with breakfast, or a larger (850 mg) tablet can be prescribed twice daily or even three times daily if needed. Dosage should always be divided because ingestion of more than 1000 mg at any one time usually provokes significant gastrointestinal adverse effects.

**Paediatrics:** Metformin can be given to paediatric diabetic patients of above 10 years of age. The usual starting dose of metformin is 500 mg twice daily with meals.

### Side Effects:

The most common side effects of metformin are gastrointestinal (anorexia, nausea, vomiting, abdominal discomfort and diarrhoea), which occur in upto 20% of patients. They are dose related, tend to occur at the onset of therapy, and are often

transient. However metformin may have to be discontinued in 3-5% of patients because of persistent diarrhoea. Absorption of vitamin B<sub>12</sub> appears to be reduced during long term metformin therapy.

### Contraindication:

Metformin is contraindicated in patients with renal disease, alcoholism, hepatic disease or conditions predisposing to tissue anoxia (e.g. chronic cardiopulmonary dysfunction) because of an increased risk of lactic acidosis induced by metformin therapy. It is also contraindicated in patient with known hypersensitivity to metformin.

### Precautions:

Metformin is known to be substantially excreted by the kidney and the risk of metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Thus, patients with serum creatinine levels above the upper limit of normal for their age should not receive metformin.

### Use in Pregnancy & Lactation:

**Pregnancy:** Safety in pregnant woman has not been established. Metformin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether metformin is secreted in breast milk. As data is not available, metformin is not recommended in breast-feeding mothers.

### Drug interactions:

Co-administration of furosemide, nifedipine, amiloride, digoxin, ranitidine, triamterene, and trimethoprim with metformin increase the plasma metformin concentration. Thus, careful patient monitoring and dose adjustment of metformin and/or the interfering drug is recommended in patients who are taking such drugs.

### Overdosage:

Hypoglycaemia has not been seen even with ingestion of up to 85 grams of metformin, although lactic acidosis has occurred in such circumstances. Hemodialysis may be useful for removal of accumulated drug from patients in whom metformin overdose is suspected.

### Storage:

Keep away from light and store at cool and dry place.

### Packaging:

**Obemet<sup>®</sup> 500:** Box containing 10 strips of 10 tablets each. Each tablet contains metformin hydrochloride BP 500 mg.

**Obemet<sup>®</sup> 850:** Box containing 5 strips of 10 tablets each. Each tablet contains metformin hydrochloride BP 850 mg



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