Composition : Extended Release Metformin Hydrochloride+Immediate Release Sitagliptin; (1000mg+50mg), (500mg+50mg) Tablet.

**Indications :** Sitagliptin and Metformin ER is a dipeptidyl peptidase-4 (DPP-4) inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin is appropriate.

**Dosage and administration** : May adjust the dosing based on effectiveness and tolerability while not exceeding the maximum recommended daily dose of 100 mg Sitagliptin and 2000 mg Metformin Extended Release. Administer once daily with a meal preferably in the evening. Gradually escalate the dose to reduce the gastrointestinal side effects due to Metformin. Maintain the same total daily dose of Sitagliptin & Metformin when changing between Sitagliptin and Metformin ER, without exceeding the maximum recommended daily dose of 2000 mg Metformin extended release. Swallow whole. Never split, crush or chwe. Or, as directed by the registered physician.

**Contraindications :** It is contraindicated in patient with known hypersensitivity to the drug, Renal disease or renal dysfunction, and acute or chronic metabolic acidosis, including diabetic ketoacidosis.

**Side effects :** Hypoglycemia, vomiting, gastrointestinal pain, diarrhea, allergic skin reactions, e.g. pruritus, erythema, urticaria, and morbilliform or maculopapular eruptions, may occur.

**Precautions :** Do not use the combination of Sitagliptin and Metformin with hepatic

## Sliptin-M ER Tablet

disease. Before initiating the combination and at least annually thereafter, assess renal function and verify as normal. May need to discontinue the combination and temporarily use insulin during periods of stress and decreased intake of fluids and food as many occur with fever, trauma, infection or surgery.

Use in pregnancy and lactation : Sliptin-M ER has been assigned to pregnancy category-B by the FDA. There are no controlled data in women pregnancy. It can be used i pregnancy if potential benefits outweigh the risk or as directed by the registered physician. Sliptin-M ER is likely to be excreted into the breast milk. A decision should be made whether to discontiune nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

**Drug interactions :** Carbonic anhydrase inhibitors should be used with caution treated with Sitagliptin and Metformin ER, as the risk of lactic acidosis may increasre. Careful patient monitoring and dose adjustment of Sitagliptin and Metformin ER and/ or the interfering drug is recommended in patients who are taking cationic medications that are excreted via the proximal renal tubular secretory system.

**Packing : Sliptin-M 1000 ER :** Each box contains 2x7's tablets in blister pack.

**Sliptin-M 500 ER :** Each box contains 2x7's tablets in blister pack.