For the use only of a Registered Medical Practitioner or hospital or a laboratory

Abridged Prescribing Information

Metformin Hydrochloride Prolonged Release Tablets IP
CETAPIN® XR

COMPOSITION: Each uncoated prolonged release tablet contains Metformin HCl IP 1000mg / 500mg
THERAPEUTIC INDICATION: As an adjunct to diet and exercise to improve glycemic control in patients with Type II diabetes.
DOSAGE AND ADMINISTRATION
Adults with normal renal function: Usual starting dose is 500mg once daily. Dosage increase should be made in increments of 500mg every 10-15 days, up to maximum 2000mg once daily. If 2000mg once daily does not achieve adequate glycemic control, 1000mg bid should be considered. If glycemic control is still not achieved patients could be switched to maximum 3000mg standard metformin.
Combination with insulin: Metformin and insulin may be used in combination therapy to achieve better blood glucose control. ***Elderly patients:*** Due to potential for decreased renal function in elderly subjects, the metformin dosage should be adjusted based on renal function. ***Renal impairment:*** GFR should be assessed before initiation of treatment with metformin and at least annually thereafter. In patients at an increased risk of further progression of renal impairment and in the elderly, renal function should be assessed more frequently, e.g. every 3-6 months. Dosing adjustment is required in case of renal impairment.

SAFETY-RELATED INFORMATION
CONTRAINDICATIONS: Known hypersensitivity to metformin hydrochloride or any excipients; any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis), diabetic pre-coma, severe renal failure (GFR<30 mL/min), acute conditions with the potential to alter renal function such as dehydration, severe infection, shock; diseases which may cause tissue hypoxia (such as decompensated heart failure, respiratory failure, recent myocardial infarction, shock); hepatic insufficiency, acute alcohol intoxication, alcoholism.
WARNINGS & PRECAUTIONS: Lactic acidosis: Metformin accumulation increases the risk of lactic acidosis**.** In case of dehydration, discontinue Cetapin® XR and contact heath care professional **Renal function:** GFR should be assessed before treatment initiation and regularly thereafter. **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. **Administration of iodinated contrast agents:** Metformin should 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. **Surgery:** Metformin must be discontinued at the time of surgery under general, spinal or epidural anaesthesia. Therapy may be restarted no earlier than 48 hours following surgery or resumption of oral nutrition and provided that renal function has been re-evaluated and found to be stable. **Other precautions**: All patients should continue their diet with a regular distribution of carbohydrate intake, overweight patients should continue their energy-restricted diet. The usual laboratory tests for diabetes monitoring should be performed regularly. Caution is advised when used in combination with insulin or other oral antidiabetics. Regular monitoring of thyroid-stimulating hormone (TSH) levels is recommended in patients with hypothyroidism. Monitoring of the vitamin B12 level is recommended. The tablet shells may be present in the faeces, this is normal.
PREGNANCY & LACTATION: When a patient plans to become pregnant and during pregnancy, it is recommended that insulin be used to maintain blood glucose levels. Breast feeding is not recommended during metformin treatment.
ADVERSE EFFECTS: Very common / common adverse events include nausea, vomiting, diarrhoea, abdominal pain, loss of appetite and taste disturbance.

For full prescribing information, please contact: Sanofi India Limited, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072.

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