

Dibeta SR

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for Dibeta SR (Metformin Hydrochloride Sustained Release Tablets IP)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Metformin is a biguanide with antihyperglycaemic effects, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycaemia. Metformin may act via 3 mechanisms: 1) reduction of hepatic glucose production by inhibiting gluconeogenesis and glycogenolysis 2) In muscle, by increasing insulin sensitivity, improving peripheral glucose uptake and utilisation and 3) delay of intestinal glucose absorption. Metformin stimulates intracellular glycogen synthesis by acting on glycogen synthase. It increases the transport capacity of all types of membrane glucose transporters (GLUT).

DOSAGE AND ADMINISTRATION: Uncoated Sustained Release Tablets of **Dibeta SR and Dibeta SR 1 GM** are used for type II diabetes and it should be swallowed whole and not to be chewed or crushed.

CONTRAINDICATION: Hypersensitivity to metformin or to any of the 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, Disease which may cause tissue hypoxia (especially acute disease, or worsening of chronic disease) such as: decompensated heart failure, respiratory failure, recent myocardial infarction, shock, Hepatic insufficiency, acute alcohol intoxication, alcoholism.

WARNINGS & PRECAUTIONS: Lactic acidosis: In case of dehydration, Medicinal products that can acutely impair renal function (such as antihypertensives, diuretics and NSAIDs). Renal function: GFR should be assessed before treatment initiation and regularly thereafter, see Metformin is contraindicated in patients with GFR<30 mL/min. Cardiac function: Patients with heart failure are more at risk of hypoxia and renal insufficiency. Elderly: Due to the limited therapeutic efficacy data in the reduction of risk or delay of type 2 diabetes in patients 75 years and older, metformin initiation is not recommended in these patients. Administration of iodinated contrast agents, Surgery, Other precautions: All patients should continue their diet with a regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet.

DRUG INTERACTION: Concomitant use not recommended: Alcohol. **Combinations requiring precautions for use:** NSAIDs, including selective cyclo-oxygenase (COX) II inhibitors, ACE inhibitors, angiotensin II receptor antagonists and diuretics, especially loop diuretics. Organic cation transporters (OCT): Co-administration of metformin with Inhibitors of OCT1, OCT2, Inducers of OCT1 and Inhibitors of both OCT1 and OCT2.

ADVERSE REACTIONS: Nausea, vomiting, diarrhoea, abdominal pain and loss of appetite, which resolve spontaneously in most cases, Lactic acidosis, Decrease of vitamin B12 absorption with, Taste disturbance, Isolated reports of liver function tests abnormalities or

hepatitis resolving upon metformin discontinuation, Skin reactions such as erythema, pruritus, urticaria.

Manufactured by:

Dibeta SR

TORRENT PHARMACEUTICALS LTD.

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East district, Gangtok, Sikkim-737 135

Dibeta SR 1 GM

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OR

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IN/DIBETA SR 500, 1000mg/AUG-21/02/ABPI

(Additional information is available on request)