DIBETA Gb

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for DIBETA Gb [Glibenclamide and Metformin Tablets I.P]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Glibenclamide is an orally active hypoglycaemic agent, which acts by stimulating insulin secretion. 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: • Reduction of hepatic glucose production by inhibiting gluconeogenesis and glycogenolysis. • In muscle, by increasing insulin sensitivity, improving peripheral glucose uptake and utilization. • And delay of intestinal glucose absorption. Metformin stimulates intracellular glycogen synthesis by acting on glycogen synthase. Metformin increases the transport capacity of all types of membrane glucose transporters (GLUTs) known to date.

INDICATIONIt is indicated for treatment of Non-insulin dependent diabetes mellitus patients poorly controlled with sulphonyl urea or biguanide alone.

DOSAGE AND ADMINISTRATION: The recommended dose is one tablet of DIBETA Gb twice daily with the morning and evening meals. The daily dose should be titrated in increments of no more than 5 mg Glibenclamide / 500 mg metformin up to the minimum effective dose to achieve adequate blood glucose control. The dose should not exceed the maximum recommended daily dose of 20 mg Glibenclamide / 2000 mg metformin.

CONTRAINDICATION: • Hypersensitivity to Glibenclamide and Metformin or to any of the excipients • Patients known to have sensitivity to other sulphonylureas and related drugs • Juvenile onset diabetes • Diabetic ketoacidosis, diabetic pre-coma and diabetic coma. • Severe infection, stress, trauma, surgical procedures or other severe conditions where the drug is unlikely to control the hyperglycaemia • Severe impairment of renal function • Moderate (stage 3b) and severe renal failure or renal dysfunction (CrCl < 45 ml/min or eGFR < 45 ml/min/1.73m2) • Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock • Hepatic impairment • Hepatic insufficiency, acute alcohol intoxication, alcoholism • 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 • Porphyria • Pregnancy • Elderly (> 70 years).

WARNINGS & PRECAUTIONS: Hypoglycaemia: all sulphonylurea drugs are capable of producing moderate or severe hypoglycaemia, particularly in the following conditions: • In patients controlled by diet alone. • In cases of overdose. • When calorie or glucose intake is insufficient • In patients with irregular mealtimes and/or missed meals • During excessive exercise • In debilitated patients • In patients with mild to moderate renal impairment. However, in long-term clinical trials patients with renal insufficiency have been treated satisfactorily using Glibenclamide at reduced doses with careful patient monitoring. • In patients with adrenal or pituitary insufficiency • In order to reduce the risk of hypoglycaemia it is therefore recommended: • To initiate treatment for non-insulin dependent diabetics by diet alone, if this is possible. • To adjust the dose of Glibenclamide according to the blood glucose response and to the 24 hour urinary glucose during the first days of treatment.

DRUG INTERACTIONS: Glibenclamide has many clinically important drug interactions: bosentan should be avoided due to increased hepatotoxicity risk, while numerous medicines can either enhance hypoglycaemia (e.g. NSAIDs, many antibiotics, antifungals, antidepressants, ACE inhibitors, beta-blockers, anticoagulants, androgens) or reduce its effect (e.g. rifamycins, diuretics, thyroid hormones, corticosteroids, oral contraceptives, chlorpromazine, diazoxide). Some drugs alter glucose tolerance or require dose adjustment (e.g. isoniazid, lithium, octreotide, ciclosporin).

Metformin use is not recommended with alcohol (risk of lactic acidosis) or around iodinated contrast media, where it must be temporarily discontinued depending on renal function; caution is also required with hyperglycaemic drugs (such as glucocorticoids and sympathomimetics) and loop diuretics due to increased lactic acidosis risk.

ADVERSE REACTIONS: Lactic acidosis, decrease of vitamin B12 absorption with decrease of serum levels during long-term use of metformin , Hypoglycaemia., Syndrome of inappropriate secretion of antidiuretic hormone, characterised by water retention and hyponatraemia, Taste disturbance, nausea, vomiting, diarrhoea, abdominal pain, heartburn, anorexia and loss of appetite, Isolated reports of liver function tests abnormalities or hepatitis, erythema, pruritus, urticaria, Rash, multiforme, erythema nodosum, bullous eruptions, pruritus, exfoliative dermatitis, photosensitivity, altered liver enzymes values, hepatitis, cholestatic jaundice, blood dyscrasias including agranulocytosis, aplastic and haemolytic anaemia, pancytopenia, leucopenia, thrombocytopenia and neutropenia, Fever, Stevens-Johnson syndrome.

MARKETED BY:

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(Additional information is available on request)