Taj Pharmaceuticals Ltd.

Glibornuride

CAS No. : 26944-48-9

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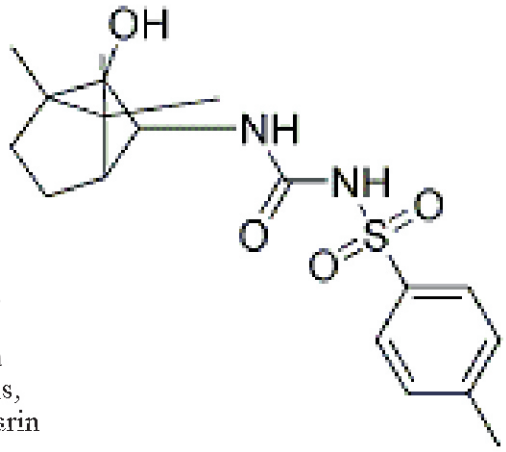
Molecular Formula: C18H26N2O4S
Formula Weight: 366.47504



Mechanism of Action

Glibornuride acts by stimulating insulin secretion and is effective only when some residual pancreatic β-cell activity is present.

Drug Interactions

Diminished hypoglycaemic effect with adrenaline, aminoglutethimide, chlorpromazine, corticosteroids, diazoxide, oral contraceptives, rifamycins and thiazide diuretics. Increased hypoglycaemic effect with ACE inhibitors, alcohol, allopurinol, some analgesics, azole antifungals, chloramphenicol, cimetidine, clofibrate and related compounds, coumarin anticoagulants, halofenate, heparin, MAOIs, octreotide, ranitidine, sulfinpyrazone, sulfonamides, tetracyclines, tricyclic antidepressants and thyroid hormones. β-blockers increase hypoglycaemia and mask typical sympathetic warning signs.

DOSAGE

Adults - In general, clinically significant responses are not seen at doses below 1500 mg per day. However, a lower recommended starting dose and gradually increased dosage is advised to minimize gastrointestinal symptoms.

The usual starting dose of Glibornuride is 500 mg twice a day or 850 mg once a day, given with meals. Dosage increases should be made in increments of 500 mg weekly or 850 mg every 2 weeks, up to a total of 2000 mg per day, given in divided doses. Patients can also be titrated from 500 mg twice a day to 850 mg twice a day after 2 weeks.

For those patients requiring additional glycemic control, Glibornuride may be given to a maximum daily dose of 2550 mg per day. Doses above 2000 mg may be better tolerated given three times a day with meals.

SIDE EFFECTS

Lactic acidosis

The most serious side effect of Glibornuride is lactic acidosis. However, this complication is rare if the contra-indications are followed, as it seems limited to those with impaired liver and/or kidney function.

Gastrointestinal

The most common side effect of Glibornuride is gastrointestinal upset. This includes diarrhoea, cramps, nausea and vomiting. In a clinical trial of 286 subjects, 53.2% of the 141 who were given Glibornuride IR (as opposed to placebo) reported diarrhoea, and 25.5% reported nausea/vomiting.

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The side effect of gastrointestinal upset can be source of severe discomfort for patients. It is very common when Glibornuride is first administered, or when the dose is increased. The discomfort can often be avoided by beginning and increasing the dose gradually. Gastrointestinal upset after prolonged, steady use is less common.

Long-term use of Glibornuride has been associated with malabsorption of vitamin B12. The dose and duration of Glibornuride use predicts B12 deficiency, and some researchers recommend screening or prevention strategies.

PRECAUTIONS

Before taking Glibornuride , tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies.

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: kidney disease, liver disease, concedure using injectable iodinated contrast material, tell your doctor that you are taking this medication. You will need to temporarily stop this medication before the time of your surgery/procedure. Consult your doctor for further instructions.You may experience blurred vision, dizziness, or drowsiness due to extremely low or high blood sugar levels. Use caution while driving, using machinery, or taking part in any other activity that requires clear vision and alertness.

Limit alcohol while using this medication to lower your risk of lactic acidosis.
It may be harder to control your blood sugar when your body is stressed (e.g., due to fever, infection, injury, or surgery). Consult your doctor because this may require a change in your treatment plan, medications, or blood sugar testing.

Kidney function declines as you grow older. This medication is removed by the kidneys. Therefore, elderly people may be at greater risk for side effects such as lactic acidosis or low blood sugar while using this drug.During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. Your doctor may substitute insulin for this drug during your pregnancy. Follow your doctor's instructions carefully.

This medication can cause changes in the menstrual cycle (promote ovulation) and increase the risk of becoming pregnant. Consult your doctor or pharmacist about the use of reliable birth control while using this medication. It is not known whether this drug passes into breast milk. This drug could have undesirable effects on a nursing infant. Therefore, breast-feeding is not recommended while using this drug.

INTERACTION

Diminished hypoglycaemic effect with adrenaline, aminoglutethimide, chlorpromazine, corticosteroids, diazoxide, oral contraceptives, rifamycins and thiazide diuretics. Increased hypoglycaemic effect with ACE inhibitors, alcohol, allopurinol, some analgesics, azole antifungals, chloramphenicol, cimetidine, clofibrate and related compounds, coumarin anticoagulants, halofenate, heparin, MAOIs, octreotide, ranitidine, sulfinpyrazone, sulfonamides, tetracyclines, tricyclic antidepressants and thyroid hormones. β-blockers increase hypoglycaemia and mask typical sympathetic warning signs.

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: drugs that may affect the kidneys' ability to remove Glibornuride from the body (e.g., cimetidine, cephalexin), "water pills"/diuretics (e.g., furosemide, thiazide diuretics such as hydrochlorothiazide).Many drugs can affect your blood sugar levels, making it more difficult to control your blood sugar.

Before you start, stop, or change any medication, talk with your doctor or pharmacist about how the medication may affect your blood sugar. Check your blood sugar levels regularly as directed by your doctor. Tell your doctor about the results and of any symptoms of high or low blood sugar. (See also Side Effects section.) Your doctor may need to adjust your anti-diabetic medication, exercise program, or diet.

Some medications (e.g., beta blockers such as propranolol) may mask the fast/pounding heartbeat you would usually feel when your blood sugar level falls too low (hypoglycemia). Other symptoms of low blood sugar such as dizziness, hunger, or sweating are unaffected by these drugs.

DRUG DESCRIPTION

Glibornuride prevents complications of neuropathy, retinopathy and nephropathy by inhibiting the build-up of glucose in the vessels. This means that the occurrence of diabetic complications might be slowed or prevented.

glibornuride is unlikely to control the hyperglycaemia; renal or hepatic impairment; porphyria; pregnancy; lactation.

Glibornuride Belongs to the class of sulfonamides, urea derivatives. Used in the treatment of diabetes.

The main use for Glibornuride is for the treatment of diabetes mellitus type 2, especially when it is concomitant with obesity and insulin resistance.

It is also being used increasingly in polycystic ovarian syndrome (PCOS) and non-alcoholic steatohepatitis, two other diseases that feature insulin resistance; these indications are still considered experimental.

Glibornuride is the only anti-diabetic drug that has been proven to reduce the complications of diabetes, as evidenced in a large study of overweight patients with diabetes.

Presentations

Glibornuride is available in 500 mg, 850 mg, and 1000 mg tablets. Doses of up to 3 g a day are commonly prescribed.

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:
http://www.tajapi.com
or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.
This leaflet was prepared by
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Mumbai (India).
MPSTJ278
Last revised: 29 August 2009