

BEZAMIDIN TABLET 200MG

DESCRIPTION

A white to off-white, round, shallow biconvex, film-coated tablet.

COMPOSITION

Each film-coated tablet contains Bezafibrate 200mg

PHARMACODYNAMICS

Bezafibrate is a fibric acid-derived hypolipidaemic agent. It lowers elevated blood triglycerides and cholesterol by lowering VLDL and LDL. In addition, bezafibrate increases HDL.

In addition, bezafibrate lowers elevated plasma fibrinogen levels, which may lead to a reduction of blood and plasma viscosity. Inhibition of platelet aggregation has also been observed.

PHARMACOKINETICS

Bezafibrate is readily absorbed from the gastrointestinal tract. Plasma protein binding is about 95% while its plasma half-life is about 2 hours. Most of a dose is excreted in the urine, about 50% as unchanged drug, the remainder as metabolites including the glucuronide conjugate. A small proportion of the dose appears in the faeces.

INDICATIONS

Bezamidin Tablet is used in conjunction with dietary and lifestyle modification in the treatment of all types of hyperlipoproteinaemia responsive to drug therapy (types IIa, IIb, III, IV and V).

It is also indicated in the treatment of secondary hyperlipidaemias associated with an underlying disorder (eg diabetes mellitus), when treatment of the underlying disorder does not result in adequate control of the hyperlipidaemic state.

DOSAGE AND ADMINISTRATION

The usual recommended dose is one film-coated tablet (200mg) three times daily, to be taken with or after meals.

In hypertriglyceridaemia or when therapeutic response is good, the dose may be reduced to one tablet twice daily.

In patients with gastric sensitivity, the dose may need to be increased gradually to maintenance level. In patients with impaired renal function, dose of bezafibrate need to be adjusted according to serum creatinine levels:

1.6-2.5mg/100ml - 1 tablet twice daily

2.6-6mg/100ml - 1 tablet every 1 or 2 days

Over 6mg/100ml - 1 tablet every third day

In dialysis patients, the recommended dose is one tablet every third day.

ROUTE OF ADMINISTRATION

Oral administration

CONTRAINDICATIONS

Contraindicated in patients with known hypersensitivity to the drug, and in patients with liver disease (except fatty liver, which occurs often in patients with hypertriglyceridemia), gallbladder disease with or without cholelithiasis.

Bezafibrate is contraindicated during pregnancy and lactation.

WARNINGS AND PRECAUTIONS

Bezafibrate therapy must be used in conjunction with dietary modifications and other measures which are beneficial in lipid disorders, such as physical exercise, weight reduction and appropriate control of other associated disorders (eg diabetes, gout).

Bezafibrate must be used with caution in patients with hypoalbuminaemic states (e.g. nephrotic syndrome) and in those with renal impairment. The dose must be reduced according to serum creatinine levels and the renal function monitored regularly. In dialysis patients, the dose of bezafibrate should be one tablet every third day.

When prescribing bezafibrate to patients who are on oestrogens or oestrogen-containing contraceptives, it must be remembered that oestrogens by themselves may cause an increase in lipid levels.

During long term therapy with bezafibrate, the possibility of cholelithiasis must be considered. Appropriate diagnostic procedures should be performed if cholelithiasis-related signs and symptoms occur.

Bezafibrate should be given concurrently with HMG CoA reductase inhibitors only when strictly indicated, and patients must be monitored closely for symptoms of myopathy. Combination therapy must be stopped as soon as symptoms of myopathy are suspected. Such combination therapy must not be used in those with predisposing factors for myopathy including renal impairment, surgery, hormonal or electrolyte imbalances.

Patient's response to bezafibrate therapy should be monitored regularly and therapy stopped if adequate response is not obtained within 3 to 4 months.

Use in children: Use of the drug in children must be very carefully considered. Specific dosage recommendation for children cannot be given.

PREGNANCY AND LACTATION

Use of bezafibrate is contraindicated during pregnancy and lactation.

INTERACTIONS WITH OTHER MEDICAMENTS

Bezafibrate may potentiate the action of coumarin-type anticoagulants. Therefore, the dosage of the anticoagulant should be reduced by 30-50 % at the start of therapy with bezafibrate and then adjusted according to blood clotting parameters.

Bezafibrate may improve glucose tolerance in diabetic patients; hence the dose of sulphonylureas and insulin may need to be adjusted during bezafibrate treatment.

Concurrent administration of bezafibrate with cholestyramine impairs bezafibrate absorption. When both drugs are prescribed, they should be administered at least 2 hours apart.

Great caution must be exercised when bezafibrate is to be prescribed concurrently with HMG CoA inhibitors (see Precautions/Warnings above).

SIDE EFFECTS

Bezafibrate is generally well tolerated. The commonest side effects during bezafibrate therapy are gastrointestinal disturbances including loss of appetite, nausea, flatulence and abdominal discomfort, which are usually transient. Other adverse effects reported occasionally include allergic skin reactions such as pruritus and urticaria and in isolated cases, generalized hypersensitivity reactions. Very rarely, headache, dizziness, alopecia and isolated cases of impotence have been reported.

Gallstones may occur rarely (please see Precautions/Warnings). A syndrome of muscular pain, cramps and muscular weakness associated with elevated creatine phosphokinase levels may also occur, particularly in patients with preexisting renal impairment.

SYMPTOMS AND TREATMENT OF OVERDOSE

In case of acute overdose, patient should be treated symptomatically and monitored for signs and symptoms due to adverse effects of the drug.

STORAGE

Store in a cool dry place below 30°C.
Keep container tightly closed.
Protect from light.
Keep medicines out of reach of children.

PRESENTATION

Blister of 10 tablets, box of 100, 250, 500 and 1000 tablets.

MANUFACTURED BY

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DATE OF REVISION

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