

BEZAMIDIN TABLET

Bezafibrate (200mg)

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What Bezamidin used for

Bezamidin Tablet is used in conjunction with dietary and lifestyle modification in the treatment of all types of hyperlipidaemia (elevated lipid/fat levels in the blood) responsive to medicinal therapy (types IIa, IIb, III, IV and V). It is also indicated in the treatment of secondary hyperlipidaemia (elevated lipid/fat levels in the blood) associated with an underlying disorder (e.g. diabetes mellitus), when treatment of the underlying disorder does not result in adequate control of the hyperlipidaemic state.

How Bezamidin works

Bezamidin belongs to a group of medicines called lipid-regulating agents, which lower high levels of cholesterol and other fats (lipids) in the blood (hyperlipidaemia). This reduces and prevents any long term effects associated with hyperlipidaemia.

Before you use Bezamidin

- When you must not use it

Do not take Bezamidin and tell your doctor if you

- are allergic (hypersensitive) to bezafibrate or any of the other ingredients in the tablets
- are taking statins (e.g. atorvastatin) and have any of

the following which may increase the risk of you developing muscle disease (weakness, wasting and pain):

- are having dialysis.
- have liver disease.
- have gall bladder disease.
- have nephrotic syndrome (a kidney disorder).
- have severely impaired kidney function.

- Before you start to use it

Check with your doctor or pharmacist before taking Bezamidin if you have any of

- the following which may increase the risk of you developing muscle disease (weakness, wasting and pain):
- impaired kidney function
 - an underactive thyroid (hypothyroidism)
 - severe infection
 - trauma
 - surgery
 - a change in the levels of hormones or chemicals in your body (seen in a blood test)
 - a high alcohol intake
 - are elderly (over 65 years old)
 - Have a family history of muscle disease.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- coumarin-type anti-coagulants e.g. warfarin (used to prevent blood clotting).
- antidiabetic medicines such as insulin (used in diabetes).
- anion exchange resins such as colestyramine (used to lower cholesterol). Bezamidin and an anion exchange resin should not be taken within 2 hours of each other.

- Statins e.g. atorvastatin (used to lower cholesterol).
- oestrogen or medicines which contain oestrogen.

How to use Bezamidin

- How much to use

Adults: Three tablets a day in divided doses (600mg bezafibrate a day).

Elderly: Your doctor may reduce the dose depending on how your kidneys are working.

Children: Not recommended.

Impaired kidney function: If you have impaired kidney function, your doctor may give you a different dose, especially if you are having dialysis.

- When to use

Swallow the tablets whole with water, after or with food.

- How long to use it

Always take Bezamidin exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

If adequate response is not obtained within 3-4 months, the doctor might stop your treatment with Bezamidin

- If you forget to use it

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take soon as you remember it and then take the next dose at the right time.

- If you use too much (overdosage)

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital emergency department or tell your doctor immediately.

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While you are using it

- Things you must do

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

- Things you must not do

If you are pregnant or lactating you should not take Bezamidin.

- Things to be careful of

Bezamidin may make you feel dizzy. Make sure you are not affected before you drive or operate machinery.

Side effects

The commonest side effects during bezafibrate therapy are decreased appetite, nausea, blotted feeling and feeling sick which are usually transient.

If you encounter any other side effects or the side effects are getting worse, please inform your doctor/pharmacist immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting)

Storage and Disposal of Bezamidin

- Storage

Store in a cool dry place below 30°C. Protect from light.

- Disposal

Medicines should not be disposed of via wastewater or

household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

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

- Ingredients

- Active ingredient

Bezafibrate

- Inactive ingredients

Sodium starch glucolate, Corn starch, Polyethylene glycol, Talc, Titanium dioxide, Povidone, Magnesium stearate, Croscarmellose sodium, Hydroxypropylmethyl cellulose, Microcrystalline cellulose, Isopropyl alcohol, Lactose, Propylene glycol, Purified water

- MAL number:

MAL19988485AS

Manufacturer

Noripharma Sdn. Bhd.
Lot 5030, Jalan Teratai,
5 ½ Miles off Jalan Meru
41050 Klang, Selangor

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
5 ½ Miles off Jalan Meru
41050 Klang, Selangor

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- March 2015

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