
PROPOSED AMENDED PATIENT INFORMATION LEAFLET (Clean)

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BISBETA 2.5 mg (tablet)

BISBETA 5 mg (tablet)

BISBETA 10 mg (tablet)

Bisoprolol fumarate (2:1)

Read all of this leaflet carefully before you start taking BISBETA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BISBETA** have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours

1. WHAT BISBETA CONTAIN

The active substance is bisoprolol fumarate.

BISBETA 2.5 mg:

Each film-coated tablet contains bisoprolol fumarate (2:1) 2.5 mg. Sugar free.

BISBETA 5 mg:

Each film-coated tablet contains bisoprolol fumarate (2:1) 5 mg. Sugar free.

BISBETA 10 mg:

Each film-coated tablet contains bisoprolol fumarate (2:1) 10 mg. Sugar free.

The other ingredients of **BISBETA** are calcium hydrogen phosphate; cellulose microcrystalline; crospovidone; magnesium stearate and silica colloidal anhydrous.

The coating material of **BISBETA** contains hypromellose; macrogol / PEG 400 and titanium dioxide (C.I. No: 77891).

2. WHAT BISBETA ARE USED FOR

BISBETA belongs to a group of medicines called beta-blockers.

BISBETA are used in combination with other medicines to treat stable chronic (long-term) moderate to severe heart failure.

3. BEFORE YOU TAKE BISBETA

Do not take BISBETA:

- If you are hypersensitive (allergic) to bisoprolol, or any of the other ingredients of **BISBETA**.
- If you are in acute heart failure or if you require injection of inotropic medicines (medicines which increase the force of contraction of the heart)
- If you have had cardiac shock (inadequate heart function)
- If you suffer from heart block and do not have a pacemaker
- If you suffer from very slow heartbeats (less than 50/minute) or sick sinus syndrome (a syndrome of slow heart beats with rapid dysrhythmics)
- If you suffer from sinoatrial block (interference of impulse to heart chamber)
- If you have very poor circulation or Raynaud's syndrome
- If you have low blood pressure
- If you suffer from an untreated phaeochromocytoma (a tumour on the adrenal glands)
- If you suffer from severe bronchial asthma, bronchitis or have severe breathing difficulties.
- If you are pregnant or breast-feeding.
- If you suffer from an overactive thyroid gland producing an excessive amount of thyroid hormones.
- If you have metabolic acidosis (a condition that occurs when the body produces too much acid or when the kidneys are not removing enough acid from the body)
- In children.

Take special care with BISBETA:

- Before taking **BISBETA**, tell your doctor if you suffer from any of the following:
 - asthma or any other lung disease.
 - diabetes mellitus (taking **BISBETA** can make it harder for you to tell when you have low blood sugar)

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- you are having desensitisation therapy for allergies
 - heartblock
 - Prinzmetal's angina (a form of unstable angina)
 - poor circulation
 - psoriasis
 - kidney disease – If you have severe kidney problems, your doctor will adjust the dosage of **BISBETA**.
 - a phaeochromocytoma (a tumour on the adrenal glands)

- Also tell your doctor if:

- you are fasting
- you are taking or receiving any other medicines such as anaesthetics, calcium antagonists, medicines used to treat heart disease and irregular heart beat such as disopyramide and verapamil, and clonidine (medicine used to treat high blood pressure, migraine and menopausal flushing).

Care is required if you are being transferred from clonidine to **BISBETA**

. If you are taking **BISBETA** and clonidine together, the

clonidine should not be stopped until several days after **BISBETA** have been withdrawn.

- you need to have any type of surgery. Tell the surgeon and anaesthetist ahead of time that you are using **BISBETA**..

- **BISBETA** may mask the signs of thyroid overactivity.

- Your doctor will monitor you regularly when you start taking **BISBETA**.

- If you have a history of severe allergic reactions that have required adrenaline,

BISBETA may make your system unresponsive to the usual effective dose of adrenaline.

- **Stopping treatment with BISBETA:** Do not stop treatment suddenly without talking to your doctor first.

Taking BISBETA with food and drink:

- **BISBETA** can be taken with food.
- Swallow the tablets with liquid.

Pregnancy and Breastfeeding:

- **BISBETA** must not be taken during pregnancy and breastfeeding.

Taking **BISBETA** shortly before birth or during labour may cause decreased muscle tone (floppiness) and low blood sugar in the newborn.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machinery:

- **BISBETA** may cause *drowsiness and dizziness. Do not drive or use any tools or machines until you know how the tablets affect you.

Taking other medicines with BISBETA:

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines.)

- Before taking **BISBETA**, tell your doctor if you are using any of the following medicines:

- Oral medicines used to treat diabetes and insulin.
- Phenothiazines (treatment of psychotic disorders)
- Medicines used to treat dysrhythmias (irregular heartbeats) e.g. disopyramide, quinidine and amiodarone
- Isoprenaline
- Guanethidine
- Reserpine (medicine for high blood pressure)
- Digoxin (medicine for heart failure)
- Anaesthetics
- Rifampicin (antibiotic to treat TB)
- Calcium channel blocker medicines (e.g. verapamil) (medicine for angina and high blood pressure)
- Clonidine (medicine for high blood pressure)

- Barbiturates (used for insomnia)
- Monoamine oxidase inhibitors (e.g. phenelzine, selegeline, tranylcypromine)
(medicine used to treat depression)
- Tricyclic antidepressants (medicines used to treat depression)
- Prostaglandin synthetase inhibitors (e.g. indomethacin)
- Ergotamine (medicine for migraines)
- Tacrine
- Other beta-blocker medicines, including eye drops.
- Medicines used to treat high blood pressure.
- Mefloquine (anti-malarial)

If you are using any of these medicines, you may not be able to take **BISBETA**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

- Before you stop taking any of your medicines, please talk to your doctor first.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **BISBETA** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE BISBETA

Always take **BISBETA** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **BISBETA** is too strong or too weak, talk to your doctor or pharmacist.

- Your doctor will tell you how many tablets to take. You should take **BISBETA** in the morning.
BISBETA can be taken with food.
- Swallow the tablet/s with some liquid and do not chew or crush them.
- **Adults and the elderly:**
When you first start taking **BISBETA** your doctor will increase the strength of the tablets you take gradually, until you receive the dose that suits you

best.

Your doctor will usually start your treatment with: **BISBETA** 1.25 mg,
once daily.

If you need a stronger dose, he will put you on:

after one week: **BISBETA** 2.5 mg, once daily,

after another week, **BISBETA** 3.75 mg, once daily,

after a further week, **BISBETA** 5 mg, once daily,

after another four weeks: **BISBETA** 10 mg, once daily (maximum dose).

- After starting treatment with **BISBETA** 1.25 mg, your doctor may observe you over a period of about 4 hours in order to monitor your blood pressure, heart rate and look for signs of worsening of heart failure.
- Your doctor may interrupt treatment or decrease the dosage step by step, if he considers it necessary.
- Treatment of stable chronic heart failure with **BISBETA** is generally a long-term treatment.

If you take more BISBETA than you should:

- Overdose symptoms may include slow heart rate and severe low blood pressure. Wheezing or shortness of breath and heart failure may occur.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
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If you forget to take BISBETA:

- Do not take a double dose to make up for a missed dose. Take the normal dose as soon as you remember and then carry on with the usual dose the next day.

Effects when treatment with BISBETA is stopped:

- **Stopping treatment with BISBETA: Do not stop treatment suddenly or change the recommended dose without talking to your doctor first.** If you need to stop treatment, it is usually done gradually, to avoid side effects.

5. POSSIBLE SIDE EFFECTS

BISBETA can have side effects.

Get emergency medical help if you have any of these **signs of an allergic reaction**:

- Hives/rash; difficulty breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side effects:

- Slow, fast or pounding heartbeats
- Chest pain
- Dizziness, lightheadedness or fainting
- Feeling short of breath, even with mild exertion
- Swelling of ankles, feet, or lower legs
- Unusual bleeding or bruising
- Hallucinations (false perceptions), loss of contact with reality
- Numbness, tingling, or cold feeling in your hands and feet

You may notice tiredness, exhaustion, dizziness and headache, especially during the first two weeks of treatment.

Other side effects include: too few white blood cells; lack of energy, fatigue, lethargy; mild headache; difficulty in sleeping; depression; problems with vision; sweating; skin reactions (rash, itching); loss of hair; low blood pressure; high blood pressure; restlessness; nausea (queasiness, feeling that one is about to vomit); vomiting; diarrhoea (frequent or loose watery stools); constipation; inflammation of the mouth; problems with hearing; muscle cramps; muscle weakness; weight gain; low blood sugar; increased levels of uric acid in the blood; increased blood levels of some fats; dizziness, lightheadedness or fainting (especially when getting up from a lying down position); nightmares; bronchospasm (constriction of air passages causing difficulty in breathing); hepatitis (inflammation of the liver) and increased liver enzymes (you would notice a yellowing of your skin or the whites of your eyes); impotence (loss of male sexual ability); runny nose; dry eyes and conjunctivitis.

Tell your doctor if any of the above side effects are severe, bothersome, do not go away or about any concerns you have while taking **BISBETA**.

Not all side effects reported for **BISBETA** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BISBETA**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF BISBETA

Store at or below 25 °C (room temperature). Do not remove the blister strip from the carton until required for use. Keep the container well closed.

Store all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF BISBETA

BISBETA 2.5 mg, BISBETA 5 mg AND BISBETA 10 mg :

Blister pack:

Tablets are packed in Push through foil: consists of 25 µm aluminium foil with 7 g/m² heat seal lacquer. One blister contains 10 tablets.

Pack size: 30's: Each carton contains 3 blisters of 10 tablets each

HDPE Container Pack:

Tablets are packed in white opaque 40 ml HDPE container and white opaque RS closure, with induction sealing wad containing 1 No. of silica gel sachet. Each container contains 30 tablets.

Pack size: 30's - One HDPE container contains 30 tablets.

8. IDENTIFICATION OF BISBETA

BISBETA 2.5 mg:

White, circular, biconvex, film-coated tablets, debossed with 'I and break line' on one side and '7' on the other side.

BISBETA 5 mg:

White, circular, biconvex, film-coated tablets, debossed with 'I and break line' on one side

and '33' on the other side.

BISBETA 10 mg:

White, circular, biconvex, film-coated tablets, debossed with 'I and break line' on one side and '34' on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

SOUTH AFRICA

BISBETA 2.5 mg: 45/5.2/0789

BISBETA 5 mg: 45/5.2/0790

BISBETA 10 mg: 45/5.2/0791

NAMIBIA

BISBETA 2.5 mg: 18/5.2/0065

BISBETA 5 mg: 18/5.2/0066

BISBETA 10 mg: 18/5.2/0067

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

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11. DATE OF PUBLICATION

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