PROPOSED PATIENT INFORMATION LEAFLET (CLEAN)

10 OCTOBER 2014

SCHEDULING STATUS:

Schedule 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

MYLAN BISOPROLOL 5 mg (film-coated tablet)

MYLAN BISOPROLOL 10 mg (film-coated tablet)

Bisoprolol fumarate

Read all of this leaflet carefully before you start taking MYLAN BISOPROLOL 5 mg & 10 mg.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **MYLAN BISOPROLOL** has 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 MYLAN BISOPROLOL 5 & 10 CONTAIN:

The active substance is bisoprolol fumarate

Each **MYLAN BISOPROLOL 5 mg** film-coated tablet contains bisoprolol fumarate 5 mg.

It also contains lactose anhydrous 30 mg (sugar)

The other ingredients are cellulose microcrystalline (Avicel PH 103), colloidal anhydrous silica, croscarmellose sodium, ferric oxide yellow, Stear-o-wet m [magnesium stearate/sodium lauryl sulphate (94/6)]
{film-coat: Opadry II yellow 40C82498 (composition of Opadry II yellow 40C82498: FD & C blue #2/Indigo carmine aluminium lake, FD & C yellow #5/tartrazine aluminium lake, HPMC 2910/hypromellose 3 cP, HPMC 2910/hypromellose 6 cP, HPMC 2910/hypromellose 50 cP, Macrogol/PEG 400, Macrogol/PEG 8000, polydextrose FCC, titanium dioxide)}

Each **MYLAN BISOPROLOL 10 mg** film-coated tablet contains bisoprolol fumarate 10 mg

It also contains: lactose anhydrous 30 mg (sugar)

The other ingredients are cellulose microcrystalline (Avicel PH 103), colloidal anhydrous silica, croscarmellose sodium, ferric oxide red, Stear-o-wet m [magnesium stearate/sodium lauryl sulphate (94/6)]
{film-coating: Opadry II orange 40C83047 (composition of Opadry II orange 40C83047: FD & C yellow #6/Sunset yellow FCF Aluminium lake, HPMC 2910/hypromellose 3 cP, HPMC 2910/hypromellose 6 cP, HPMC 2910/hypromellose 50 cP, iron oxide yellow, Macrogol/PEG 400, Macrogol/PEG 8000, polydextrose FCC, titanium dioxide)}

2. WHAT MYLAN BISOPROLOL IS USED FOR:

MYLAN BISOPROLOL is used to treat mild to moderate high blood pressure and angina pectoris (chest pain caused by blockages in the arteries to the heart muscle).

3. BEFORE YOU TAKE MYLAN BISOPROLOL:

Do not take MYLAN BISOPROLOL:

• If you have heart failure that suddenly becomes worse and / or that may require hospital treatment.
• If you have a slow heart rate and/or other heart disorders.
• If you have a slow or irregular heart rate (less than 50 beats per minute). Ask your doctor if you are not sure.
• Very low blood pressure.
• You have severe asthma or sever chronic lung disease.
• You have severe blood circulation problem in your limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue.
• You have untreated phaeochromocytoma, a rare tumour of the adrenal gland (medulla).
• You have metabolic acidosis, a condition when there is too much acid in the blood.
• If your thyroid is overactive.

• If you are allergic (hypersensitive) to **MYLAN BISOPROLOL 5 & 10** or any of the other ingredients in the film-coated tablets.

• If you are pregnant or breast-feeding (see **Pregnancy and Breast-feeding**).

MYLAN BISOPROLOL 5 & 10 is not indicated for use in children below 18 years.

Take special care with MYLAN BISOPROLOL:

• Safety and efficacy in children below 18 years have not been established.

• If you are going to be given a general anaesthetic during an operation – tell your doctor that you are taking **MYLAN BISOPROLOL.** Your doctor will tell you how to stop taking **MYLAN BISOPROLOL** before the operation.

• If you have any heart disorders.

• If you have any kidney disorders.

• If you are taking **MYLAN BISOPROLOL** together with certain heart medicines, such as disopyramide.

• If you are taking **MYLAN BISOPROLOL** and clonidine, a medicine to lower high blood pressure (see **"Taking other medicines with MYLAN BISOPROLOL").**

• If you have phaeochromocytoma (a rare tumour of the adrenal gland). Your doctor will need to treat this before prescribing **MYLAN BISOPROLOL**.

• If you have kidney disorders or you are elderly your doctor may reduce your dose of **MYLAN BISOPROLOL.**

• If you have diabetes. **MYLAN BISOPROLOL** can hide the symptoms of low blood sugar.

• If you are taking verapamil, a medicine to treat high blood pressure and certain heart conditions (see **"Taking other medicines with MYLAN BISOPROLOL").**

• If you are taking **MYLAN BISOPROLOL** and digoxin used to treat heart failure and irregular heart beats or heart rhythm, your condition will be monitored (see **"Taking other medicines with MYLAN BISOPROLOL").**

• If you are taking mefloquine, a medicine used for malaria, as this may increase the risk of heart disorders (see **"Taking other medicines with MYLAN BISOPROLOL").**

• If you take **MYLAN BISOPROLOL** you must not suddenly stop taking the tablets as your heart condition could get worse. If you want to stop taking **MYLAN BISOPROLOL**; your doctor will advise you how to gradually discontinue the treatment.

• If you have (or have had) psoriasis (a recurring skin rash).

Taking MYLAN BISOPROLOL with food and drink:

MYLAN BISOPROLOL may be taken with food or on an empty stomach.

Pregnancy and Breast-feeding:

There is a risk that **MYLAN BISOPROLOL** can harm your baby if it is used during pregnancy. If you are pregnant or plan to become pregnant you should

tell your doctor. He or she will determine whether you can take **MYLAN BISOPROLOL** during pregnancy. It is not known whether **MYLAN BISOPROLOL** passes in to breast milk. Therefore, breast-feeding is not recommended during treatment with **MYLAN BISOPROLOL**.

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **MYLAN BISOPROLOL**.

Driving and using machinery:

• **MYLAN BISOPROLOL** may make you feel drowsy and dizzy

• You must make sure how you feel before driving or operating machinery.

Important information about some of the ingredients of MYLAN BISOPROLOL:

MYLAN BISOPROLOL contains lactose which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars) talk to your doctor before taking **MYLAN BISOPROLOL** tablets.

Taking other medicines with MYLAN BISOPROLOL:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **MYLAN BISOPROLOL** with these medicines may cause undesirable interactions.

Always tell your healthcare professional if you are taking any other medicines.

• If **MYLAN BISOPROLOL** is taken with medicines for controlling blood pressure or medicines for treating heart disorders (such as clonidine, disopyramide, verapamil) it may cause serious adverse reactions.
• Phenothiazines (medicines used to treat mental illnesses).
• Medicines to control blood sugar.
• Rifampicin (a medicine for the treatment of infections).
• Ergotamine derivatives (medicines to treat severe headaches or migraines).
• When **MYLAN BISOPROLOL** is taken with medicines with blood lowering potential (for instance tricyclic antidepressant medicines and barbiturate medicines which are used to treat epilepsy) it may increase the risk of low blood pressure.
• Mefloquine (a medicine for malaria may increase the risk of heart disorders).
• Certain antidepressant medicines known as monoamine oxidase inhibitors will enhance the low blood pressure effect of **MYLAN BISOPROLOL.**
• Medicines used for certain eye disorders such as glaucoma (increased pressure in the eye) or used to widen the pupil of the eye.
• Digoxin (a medicine to treat heart disorders).
• Verapamil (a medicine to treat heart conditions).

4. HOW TO TAKE MYLAN BISOPROLOL [~~5 & 10~~]:

Do not share medicines prescribed for you with any other person.

Always take **MYLAN BISOPROLOL** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Adults:

5 to10 mg once a day in the morning, with or without food.

Your doctor will adjust the dosage according to your response and tolerance.

The maximum dose that is recommended daily is 20 mg.

Your doctor will tell you how long your treatment with **MYLAN BISOPROLOL** will last. Do not stop treatment early because if you have the impression that the effect of **MYLAN BISOPROLOL** is too strong or too weak, tell your doctor or pharmacist.

If you take more MYLAN BISOPROLOL than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

If you forget to take a dose of MYLAN BISOPROLOL:

Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with MYLAN BISOPROLOL is stopped:

Do not stop taking **MYLAN BISOPROLOL** suddenly or change the recommended dose without talking to your doctor first. If you need to stop treatment, it must be done gradually to avoid side-effects.

5. POSSIBLE SIDE-EFFECTS:

MYLAN BISOPROLOL can have side-effects.

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

If any of the following happens, stop taking **MYLAN BISOPROLOL** and call your doctor immediately or go to the casualty department at your nearest hospital:

• Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing

• Rash or itching

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to **MYLAN BISOPROLOL**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

• Slow pulse rate and heart disorders such heart failure, heart block, irregular heartbeat, worsening of heart failure causing increased breathlessness and/or retention of fluid.
• High blood pressure; symptoms of blockage of the main blood vessels to the legs

These are all serious side-effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent: Low blood pressure; cold hands and/or feet
Less frequent: Changes in blood test results showing various disorders such as reduced number of platelets in your blood, leading to an increased risk of bruising or bleeding and risk of infection
• Low blood sugar; increase in uric acid and cholesterol levels
• Sleep disorders; depression; hallucinations (imagining things); behavior disorders; confusion; nightmares
• Tiredness; dizziness; headache; restlessness; pins and needles; anxiety; coma; seizures (fits)
• Vision (seeing) disorders; reduced tear flow (can be a problem if you wear contact lenses)
• Hearing disorders

• Lung disorders including breathing problems in patients with asthma or chronic lung disease; blocked, runny nose; shortness of breath; fibrous tissue of the lung; pleurisy and inflammation of the lung
• Nausea; vomiting; diarrhoea; constipation; abdominal (stomach) cramping; inflammation of the mouth; taste disturbances
• Changes in blood test results for liver enzymes and liver toxicity
• Hair loss; rashes; itching; worsening of the skin condition psoriasis or the appearance of a similar dry, scaly rash
• Muscle cramps; muscle disorders; muscle weakness
• Reduced sexual performance
• General feeling of discomfort**;** illness or weakness; weight gain

6. STORING AND DISPOSING OF MYLAN BISOPROLOL:

STORE ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Store at or below 25 ºC in the original packaging. Keep the container tightly closed.

Blisters to be kept in the carton until required for use.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF MYLAN BISOPROLOL 5 & 10:

Blister pack comprising of clear transparent PVC film with backing of aluminium foil coated with heat seal lacquer. Blister strips packaged in an outer carton.

High density polyethylene (HDPE) bottle pack consisting of a white HDPE bottle with white opaque cap and with a desiccant and packaged into an outer carton.

Pack sizes of 30's.

8. IDENTIFICATION OF MYLAN BISOPROLOL 5 & 10:

MYLAN BISOPROLOL 5: Pale yellow, oval, biconvex film coated tablets with side notches and debossed with "BL & 4" on either side of the scoreline on one side and "M" on the other side.

MYLAN BISOPROLOL 10: Pale orange to light orange, oval, biconvex film coated tablets with side notches and debossed with "BL & ^" on either side of the scoreline on one side and "M" on the other side.

9. REGISTRATION NUMBERS:

MYLAN BISOPROLOL 5: 45/5.2/0525

MYLAN BISOPROLOL 10: 45/5.2/0526

10. NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:

Mylan (Pty) Ltd

Building 6, Greenstone Hill Office Park

Emerald Boulevard

MODDERFONTEIN, 1645

Republic of South Africa

11. DATE OF PUBLICATION:

To be advised