

# NEW ZEALAND CONSUMER MEDICINE INFORMATION

## BISOPROLOL MYLAN

*Bisoprolol fumarate Film Coated Tablets 2.5, 5 & 10 mg*



### What is in this leaflet

Please read this leaflet carefully before you start taking BISOPROLOL MYLAN.

This leaflet answers some common questions about BISOPROLOL MYLAN.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking BISOPROLOL MYLAN against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

### What BISOPROLOL MYLAN is used for

BISOPROLOL MYLAN is used:

- to treat stable chronic heart failure (CHF) in combination with other medicines suitable for this condition.
- In treatment of coronary heart disease and chest pain (angina pectoris) caused by shortage of oxygen in the heart muscle
- to treat essential hypertension (high blood pressure)

BISOPROLOL MYLAN contains the active ingredient bisoprolol fumarate. It belongs to a group of medicines called beta blockers.

These medicines work by affecting the body's response to some nerve impulses, especially in the heart. As a result, bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

Your doctor may have prescribed this medicine for another reason.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

This medicine is available only with a doctor's prescription.

### Before you take BISOPROLOL MYLAN

#### *When you must not take it*

**Do not take BISOPROLOL MYLAN if you have an allergy to:**

- any medicine containing bisoprolol fumarate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take BISOPROLOL MYLAN if you have one of the following heart problems:**

- acute heart failure
- worsening heart failure requiring injection of medicines into a vein, that adjusts the force of contraction of the heart.
- cardiogenic shock (a serious heart condition

caused by very low blood pressure)

- irregular or abnormal heartbeat
- slow heart rate (less than 60 beats/min before the start of therapy)
- low blood pressure (systolic blood pressure less than 100 mg Hg)

**Do not take BISOPROLOL MYLAN if you have:**

- severe asthma or severe chronic lung disease
- severe blood circulation problems (such as Raynaud's syndrome, a condition that may cause your fingers and toes to tingle or turn pale or blue)
- untreated phaeochromocytoma (a rare tumour of the adrenal gland, which sits near the kidney)
- metabolic acidosis (too much acid in the blood, which may cause rapid and/or shallow breathing)

**Do not give this medicine to a child.**

Safety and effectiveness in children have not been established.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

#### *Before you start to take it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- asthma
- difficulty in breathing
- wheezing or coughing
- diabetes mellitus
- strict fasting
- Prinzmetal's angina (can cause pain or tightness in the chest)
- peripheral arterial occlusive disease (narrowing or blockage of an artery)
- psoriasis (skin disease with thickened patches of red skin, often with silvery scales)
- thyroid disorders
- allergies, bisoprolol may make it more likely that you experience an allergic reaction, or such reaction may be more severe.
- kidney or liver problems

**Tell your doctor if you are going to have:**

- desensitisation therapy (for example for the prevention of hay fever), because bisoprolol may make it more likely that you experience an allergic reaction, or such reaction may be more severe.
- general anaesthesia

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

Your doctor can discuss with you the risks and benefits involved.

It may affect your developing baby if you take it during pregnancy.

The active ingredient in BISOPROLOL MYLAN may pass into breast milk and there is a possibility that your baby may be affected.

**Tell your doctor if you are lactose intolerant.**

This medicine contains lactose.

**If you have not told your doctor about any of the above, tell them before you start taking BISOPROLOL MYLAN.**

## **Taking other medicines**

**Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.**

You should also tell any health professional who is prescribing a new medication for you that you are taking BISOPROLOL MYLAN.

Some medicines may interfere with BISOPROLOL MYLAN. These include:

- calcium antagonists used to treat high blood pressure, chest pain or irregular heartbeat such as verapamil, diltiazem, nifedipine, felodipine and amlodipine
- medicines to treat changes in the rhythm or rate of the heart beat such as quinidine, disopyramide, flecainide, amiodarone and propafenone
- certain medicines used to treat high blood pressure such as clonidine, methyldopa, moxonidine, rilmenidine. However, do not stop taking these medicines without checking with your doctor first.
- locally applied beta-blockers (e.g. eye drops for glaucoma treatment)
- parasympathomimetic medicines (such as carbachol)
- insulin or other medicines used to treat diabetes.
- anaesthetics including lidocaine or barbiturates (for example, during surgery)
- cardiac glycosides, used to treat heart failure
- NSAIDs (Non-steroidal anti-inflammatory medicines) such as ibuprofen used to treat pain and inflammation
- medicines that are used to treat acute heart problems such as isoprenaline and dobutamine
- noradrenaline (norepinephrine) used to treat low blood pressure
- adrenaline (epinephrine) used to treat anaphylaxis,

cardiac arrest. and severe asthma attacks

- any medicine, which can lower blood pressure as a desired or undesired effect such as medicines to treat high blood pressure and certain medicines for depression (tricyclic antidepressants such as imipramine or amitriptyline)
- certain medicines used to treat epilepsy (such as phenytoin or barbiturates (such as phenobarbital)
- certain medicines to treat mental illness characterized by a loss of contact with reality (phenothiazines)
- moxisylylate used to treat Raynaud's disease
- mefloquine used to treat malaria
- monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide, used to treat depression

These medicines may be affected by BISOPROLOL MYLAN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## **How to take BISOPROLOL MYLAN**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

### **How much to take**

Treatment for stable chronic heart failure will normally be started at a low dose and increased gradually. Your doctor will decide how to increase the dose, and this may

normally be done in the following way:

- 1.25 mg once daily for 1 week, if well tolerated increase to
- 2.5 mg once daily for a further week, if well tolerated increase to
- 3.75 mg once daily for a further week, if well tolerated increase to
- 5 mg once daily for the 4 following weeks, if well tolerated increase to
- 7.5 mg once daily for the 4 following weeks, if well tolerated increase to
- 10 mg once daily for the maintenance therapy.

The maximum recommended dose is 10 mg once daily.

For patients with Hypertension and/or angina pectoris the usual dose is 10 mg once daily with a maximum recommended dose of 20 mg per day.

Depending on how well you tolerate the medicine, your doctor may also decide to lengthen the time between dose increases.

If your condition gets worse or you no longer tolerate the drug, it may be necessary to reduce the dose again or to interrupt treatment.

In some patients a maintenance dose lower than 10 mg bisoprolol may be sufficient. Your doctor will tell you what to do.

If you have to stop treatment entirely, your doctor will usually advise you to reduce the dose gradually, as otherwise your condition may become worse.

## ***How to take it***

**Swallow the tablets whole with a full glass of water. The tablets should not be chewed.**

## ***When to take it***

**Take your medicine in the morning.**

It does not matter if you take this medicine before or after food.

## ***How long to take it***

**Continue taking your medicine for as long as your doctor tells you.**

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

## ***If you forget to take it***

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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## **While you are taking BISOPROLOL MYLAN**

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### ***Things you must do***

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking BISOPROLOL MYLAN.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.**

## ***Things you must not do***

**Do not take BISOPROLOL MYLAN to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine.

## ***Things to be careful of***

**Be careful driving or operating machinery until you know how BISOPROLOL MYLAN affects you.**

This medicine may cause dizziness, light-headedness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol, dizziness or light-headedness and tiredness may be worse.

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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## In case of overdose

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### *If you take too much (overdose)*

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much BISOPROLOL MYLAN. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

Symptoms of an overdose may include slowed/irregular heart rate, low blood pressure, severe difficulty in breathing, feeling dizzy or trembling (due to decreased blood sugar).

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking BISOPROLOL MYLAN.**

This medicine helps most people, but it may have unwanted side effects in a few people.

**All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- headache
- stomach or intestine problems such as nausea, vomiting, diarrhoea and/or constipation
- feeling of coldness or numbness in the hands or feet
- tiredness
- unusual weakness
- muscle weakness or cramps
- sleep disturbances

- dizziness when standing up
- fainting
- reduced tear flow
- hearing problems
- runny nose or hay fever
- impaired erection
- nightmares
- psoriasis (red or scaly skin)
- hair loss

The above list includes the more common side effects of your medicine. They are usually mild.

**Tell your doctor as soon as possible if you notice any of the following:**

- changes in mood such as feeling low.
- breathing difficulties in patients with bronchial asthma or a history of obstructive airways
- slowing of heart rate
- irregular heart beat
- feeling dizzy or weak
- low blood pressure
- yellowing of the skin and/or eyes, sometimes accompanied by feeling sick and loss of appetite, nausea, fever, itching, light coloured bowel motions or dark urine.
- hallucinations
- irritation and redness of the eye (conjunctivitis)

The above list includes serious side effects that may require medical attention.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- worsening of heart failure (can include shortness of breath and/or swelling of the feet or legs)
- allergic like reactions such as itching, flush or rash

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Some side effects (for example, changes in cholesterol

or changes in function of the liver) can only be found when your doctor does tests from time to time to check your progress.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

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## After taking BISOPROLOL MYLAN

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### *Storage*

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

Do not store BISOPROLOL MYLAN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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### *What it looks like*

BISOPROLOL MYLAN 2.5 mg – Grey, oval, biconvex film coated tablets with side notches and debossed with 'BL & M' on either side of the scoreline on one side and '2.5' on the other side

BISOPROLOL MYLAN 5 mg – Pale yellow, oval, biconvex film coated tablets with side notches and debossed with 'BL & M' on either side of the scoreline on one side and '5' on the other side

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

## ***Ingredients***

### Active ingredient(s):

BISOPROLOL MYLAN contains 2.5, 5 or 10 mg of bisoprolol fumarate as the active ingredient.

### Inactive ingredient(s):

BISOPROLOL MYLAN also contains:

- Microcrystalline cellulose
- Lactose anhydrous
- Silica (colloidal anhydrous)
- Magnesium stearate
- Sodium lauryl sulphate
- Croscarmellose sodium
- Titanium dioxide
- Polydextrose
- Hypromellose
- macrogol
- Iron oxide yellow
- Iron oxide red (2.5 mg & 10 mg only)
- Iron oxide black (2.5 mg & 5 mg only)
- Sunset yellow (10 mg only)

BISOPROLOL MYLAN is gluten-free.

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## **If you want to know more**

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Should you have any questions regarding this product, please contact your pharmacist or doctor.

### ***Who supplies this medicine***

BISOPROLOL MYLAN is supplied in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland

NEW ZEALAND

Telephone: 0800 579 811

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## **Date of Preparation**

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04 August 2020.

(Based on datasheet dated 27 April 2020)