

# BILKATE 5mg Tablet

Nebivolol hydrochloride eq. to Nebivolol (5 mg)

## **What is in this leaflet**

1. What Bilkate is used for
2. How Bilkate works
3. Before you use Bilkate
4. How to use Bilkate
5. While you are using it
6. Side effects
7. Storage and Disposal of Bilkate
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

## **What Bilkate 5mg Tablet is used for**

Bilkate is used to treat raised blood pressure (hypertension).

Bilkate is also used to treat mild and moderate chronic heart failure in patients aged 70 or over, in addition to other therapies.

## **How Bilkate 5mg Tablet works**

Bilkate tablets contains *nebivolol*, a cardiovascular drug belonging to the group of selective beta-blocking agents (i.e. with a selective action on the cardiovascular system). It prevents increased heart rate, controls heart pumping strength. It also exerts a dilating action on blood vessels, which contributes as well to lower blood pressure.

## **Before you use Bilkate 5mg Tablet**

### **-When you must not use it**

Do not take Bilkate 5mg Tablet

- if you are allergic (hypersensitive) to nebivolol or any of the other ingredients of Bilkate
- if you have one or more of the following disorders:
  - low blood pressure
  - serious circulation problems in the arms or legs
  - very slow heartbeat (less than 60 beats per minute)
  - certain other serious heart rhythm problems (e.g. 2nd and 3rd degree atrioventricular block, heart conduction disorders).
- heart failure, which has just occurred or which has recently become worse, or you are receiving treatment for circulatory shock due to acute

- heart failure by intravenous drip feed to help your heart work
- asthma or wheezing (now or in the past)
- untreated phaeochromocytoma, a tumour located on top of the kidneys (in the adrenal glands)
- liver function disorder
- a metabolic disorder (metabolic acidosis), for example, diabetic ketoacidosis.

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

Take special care with Bilkate 5mg tablets

Inform your doctor if you have or develop one of the following problems:

- abnormally slow heartbeat
- a type of chest pain due to spontaneously occurring heart cramp called Prinzmetal angina
- untreated chronic heart failure
- 1st degree heart block (a kind of light heart conduction disorder that affects heart rhythm)
- poor circulation in the arms or legs, e.g. Raynaud's disease or syndrome, cramp-like pains when walking
- prolonged breathing problems
- diabetes: This medicine has no effect on blood sugar, but it could conceal the warning signs of a low sugar level (e.g. palpitations, fast heartbeat).
- overactive thyroid gland: This medicine may mask the signs of an abnormally fast heart rate due to this condition
- allergy: This medicine may intensify your reaction to pollen or other substances you are allergic to
- psoriasis (a skin disease - scaly pink patches)
- if you have to have surgery, always inform your anaesthetist that you are on Bilkate 5mg tablets before being anaesthetised.

If you have serious kidney problems do not take Bilkate 5mg tablets for heart failure and tell your doctor.

You will be regularly monitored at the beginning of your treatment for

chronic heart failure by an experienced physician (see 'How to Take').

This treatment should not be stopped abruptly unless clearly indicated and evaluated by your doctor (see 'How to Take').

### **- Children and adolescents**

Because of the lack of data on the use of the product in children and adolescents, Bilkate 5mg tablets is not recommended for use in them.

### **- 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. Certain medicines cannot be used at the same time, while other drugs require specific changes (in the dose, for example).

Always tell your doctor if you are using or receiving any of the following medicines in addition to Bilkate 5mg tablets:

- Medicines for controlling blood pressure or medicines for heart problems (such as amiodarone, amlodipine, cibenzoline, clonidine, digoxin, diltiazem, disopyramide, felodipine, flecainide, guanfacin, hydroquinidine, lacidipine, lidocaine, methyldopa, mexiletine, moxonidine, nicardipine, nifedipine, nimodipine, nitrendipine, propafenone, quinidine, rilmenidine, verapamil).
- Sedatives and therapies for psychosis (a mental illness) e.g. barbiturates (also used for epilepsy), phenothiazine (also used for vomiting and nausea) and thioridazine.
- Medicines for depression e.g. amitriptyline, paroxetine, fluoxetine.
- Medicines used for anaesthesia during an operation.
- Medicines for asthma, blocked nose or certain eye disorders such as glaucoma (increased pressure in the eye) or dilation (widening) of the pupil.
- Baclofen (an antispasmodic drug); Amifostine (a protective

# BILKATE 5mg Tablet

Nebivolol hydrochloride eq. to Nebivolol (5 mg)

medicine used during cancer treatment)

All these drugs as well as nebivolol may influence the blood pressure and/or heart function.

Medicines for treating excessive stomach acid or ulcers (antacid drug), e.g. cimetidine: you should take Bilkate 5mg tablets during a meal and the antacid drug between meals.

## - Pregnancy and breast-feeding

Bilkate 5mg tablet should not be used during pregnancy, unless clearly necessary.

It is not recommended for use while breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

## **How to use Bilkate 5mg Tablet**

Always take Bilkate 5mg Tablet exactly as your doctor has told you. You should check with your doctor if you are not sure.

Bilkate 5mg Tablet may be taken before, during or after the meal, but, alternatively, you can take it independently of meals. The tablet is best taken with some water.

## - Treatment of raised blood pressure (hypertension)

The usual dose is 1 tablet per day. The dose should be taken preferably at the same time of the day.

Elderly patients and patients with a kidney disorder will usually start with 2.5mg daily.

The therapeutic effect on blood pressure becomes evident after 1-2 weeks of treatment. Occasionally, the optimal effect is reached only after 4 weeks.

## -Treatment of chronic heart failure

Your treatment will be started and closely supervised by an experienced physician.

Your doctor will start your treatment with 1.25mg per day. This may be increased after 1-2 weeks to 2.5mg per day, then to 1 tablet per day and then to 2 tablets per day until the correct dose is reached for you. Your doctor will prescribe the dose that is right for you at each step and you

should closely follow his/her instructions.

The maximum recommended dose is 2 tablets (10mg) a day.

You will need to be under the close supervision for 2 hours by an experienced physician when you start treatment and every time your dose is increased.

Your doctor may reduce your dose if necessary.

You should not stop treatment abruptly as this can make your heart failure worse.

Patients with serious kidney problems should not take this medicine.

Take your medicine once daily, preferably at about the same time of day.

Your doctor may decide to combine Bilkate with other medicines to treat your condition.

Do not use in children or adolescents.

## - When to use it

Bilkate 5mg tablet can be taken with food or on an empty stomach, but the tablet is best taken with some water.

## - How long to use it

You should always consult with your doctor before stopping Bilkate 5mg tablet treatment, whether you are taking it for high blood pressure or chronic heart failure.

You should not stop Bilkate 5mg tablet treatment abruptly as this can temporarily make your heart failure worse. If it is necessary to stop Bilkate 5mg tablet treatment for chronic heart failure, the daily dose should be decreased gradually, by halving the dose, at weekly intervals.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## - If you forget to use it

If you forget a dose of Bilkate 5mg tablet, but remember a little later on that

you should have taken it, take that day's dose as usual. However, if a long delay has occurred (e.g. several hours), so that the next due dose is near, skip the forgotten dose and take the next, scheduled, normal dose at the usual time. Do not take a double dose. Repeated skipping, however, should be avoided.

## - If you use too much (overdose)

If you accidentally take an overdose of this medicine, tell your doctor or pharmacist immediately. The most frequent symptoms and signs of a Bilkate 5mg tablet overdose are very slow heart beat (bradycardia), low blood pressure with possible fainting (hypotension), breathlessness such as in asthma (bronchospasm), and acute heart failure.

You can take activated charcoal (which is available at your pharmacy) while you wait for the arrival of the doctor.

## **While you are using it**

### - Things you must do

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### - Things you must not do

You should always consult with your doctor before stopping Bilkate treatment.

### - Things to be careful of

This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### Driving or operating machinery

This medicine may cause dizziness or fatigue. If affected, do not drive or operate machinery.

## **Side effects**

Like all medicines, Bilkate can cause side effects, although not everybody gets them.

When Bilkate 5mg tablet is used for the treatment of raised blood pressure, the possible side effects are:

# BILKATE 5mg Tablet

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- headache, dizziness, tiredness, an unusual itching or tingling feeling, diarrhea, constipation, nausea, shortness of breath, swollen hands or feet
- slow heartbeat or other heart complaints, low blood pressure, cramp-like leg pains on walking, abnormal vision, impotence, feelings of depression, digestive difficulties (dyspepsia), gas in stomach or bowel, vomiting, skin rash, itchiness, breathlessness such as in asthma, due to sudden cramps in the muscles around the airways (bronchospasm), nightmares
- fainting, worsening of psoriasis (a skin disease – scaly pink patches)
- whole-body allergic reactions, with generalized skin eruption (hypersensitivity reactions), rapid-onset swelling, especially around the lips, eyes, or of the tongue with possible sudden difficulty breathing (angioedema)

For chronic heart failure, the following side effects were seen:

- slow heartbeat, dizziness
- worsening of heart failure, low blood pressure (such as feeling faint when getting up quickly), inability to tolerate this medicine, a kind of light heart conduction disorder that affects heart rhythm (1<sup>st</sup> degree AV-block)
- swelling of the lower limbs (such as swollen ankles).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [nptra.gov.my](http://nptra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of Bilkate 5mg Tablet

### -Storage

Keep medicines out of reach of children.

Store at temperature of not more than 30°C.

### -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 protect the environment.

## Product Description

### - *What it looks like?*

White, round, biconvex tablet with engraved NB on one side and plain on the other.

The tablet is not meant to be split and should be swallowed whole.

### - *Ingredients*

#### - Active ingredient:

*Nebivolol hydrochloride eq. to Nebivolol*

#### - Inactive ingredients:

*Lactose monohydrate, Pregelatinized corn starch, Croscarmellose sodium, Povidone (PVP K-30), Polyethylene glycol (PEG 6000), Polysorbate 80, Purified water, Isopropyl alcohol, Colloidal silicon dioxide, Magnesium stearate*

### - *MAL Number:* -

MAL23066017AZ

## Manufacturer

UNISON LABORATORIES CO., LTD.  
39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao, Chachoengsao 24000 Thailand

## Product Registration Holder

MEDISPEC (M) SDN. BHD.  
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## Date of Revision

27/07/2023

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