

## APPROVED PATIENT INFORMATION LEAFLET FOR NEBILET 5 mg

**SCHEDULING STATUS:** **S3**

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**NEBILET 5 mg [Nebivolol 5 mg]**

**(TABLET)**

**Read all of this leaflet carefully before you start taking NEBILET:**

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **NEBILET 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 NEBILET CONTAINS:**

The active substance is nebivolol hydrochloride equivalent to 5 mg nebivolol per tablet.

Contains sugar: lactose 141,75 mg.

The other ingredients are: colloidal anhydrous silica, croscarmellose sodium, hypromellose, magnesium stearate, maize starch, microcrystalline cellulose and polysorbate 80.

#### **2. WHAT NEBILET IS USED FOR:**

**NEBILET** belongs to a group of medicines known as selective beta blocking agents that act selectively on the cardiovascular system. These medicines act by lowering blood pressure, preventing increased heart rate and controlling heart pumping strength. It also exerts a dilating action on blood vessels, which contributes as well to lower blood pressure.

**NEBILET** is used to treat high blood pressure (or hypertension).

It is also used in the treatment of stable mild to moderate chronic heart failure in addition to standard therapies in elderly patients > 70 years.

### **3. BEFORE YOU TAKE NEBILET:**

#### **Do not take NEBILET if:**

- You are hypersensitive (allergic) to nebivolol or any of the other ingredients of NEBILET
- You have impaired liver functioning
- You are pregnant or breastfeeding
- You have low blood pressure
- You have heart problems such as very slow heartbeat, irregular heart rate
- You have had a recent heart failure, or exacerbation of an existing heart condition
- You have serious circulation problems in the arms or legs
- You have asthma
- You are under verapamil therapy
- You have metabolic acidosis
- You are a child. Do not give **NEBILET** to children as safety and efficacy have not been established.

#### **Take special care with NEBILET:**

##### *Allergies:*

**NEBILET** can worsen your sensitivity to allergy causing substances and the severity of those allergic reactions.

##### *Cardiovascular:*

**NEBILET** will only be prescribed for you

Tell your doctor if you have untreated chronic heart failure because taking **NEBILET** may worsen your condition.

Tell your doctor if you develop:

- A type of chest pain due to spontaneously occurring heart cramp called Prinzmetal angina
- 1<sup>st</sup> 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

Do not discontinue **NEBILET** therapy abruptly without consulting your doctor, your doctor will advise you on how to discontinue treatment without putting yourself at risk of more heart associated problems.

#### *Metabolic/Endocrinological:*

Tell your doctor if you have the following metabolic diseases:

- Diabetes: warning signs (abnormal or irregular heartbeats) of low blood sugar may be concealed
- Overactive thyroid gland: **NEBILET** may mask the signs of an overactive thyroid gland
- Abrupt withdrawal may intensify symptoms.

#### *Respiratory:*

Inform your doctor if you are suffering from asthma, bronchitis and other chronic respiratory diseases as treatment with **NEBILET** can cause mild to severe cases of breathing difficulties.

#### *Anaesthesia:*

If you are already taking **NEBILET** and need to have surgery, inform your doctor before you are anaesthetised.

#### *Other:*

Psoriasis, a skin condition distinguished by scaly pink patches, may be aggravated. Take **NEBILET** with caution if you have or had psoriasis, also inform your doctor about it.

Tell your doctor if you are suffering from kidney impairment as you are not supposed to be taking **NEBILET** for heart failure.

**Taking NEBILET with food and drink:**

**NEBILET** may be taken with or without food. The tablet is best taken with some water.

**Pregnancy and breastfeeding:**

**If you are pregnant or breastfeeding your baby while taking NEBILET, please consult your doctor, pharmacist or other healthcare professional for advice.**

Do not take **NEBILET** while you are pregnant or breastfeeding.

**Driving and using machinery:**

You may experience side effects such as dizziness and fatigue which may impair your ability to drive and use machines. Do not drive or use machines if you are affected by these side effects.

**Important information about some of the ingredients of NEBILET:**

**NEBILET** contains lactose as an ingredient. Do not take **NEBILET** if you are lactose intolerant or you have a history of being intolerant to some sugars. Seek advice from your doctor if unsure.

**Taking other medicines with NEBILET:**

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

Always tell your doctor if you are taking any of the following medicines in addition to **NEBILET** as concomitant use may influence your blood pressure and heart function:

- Medicines for controlling the 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, nifedipine, 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 medicine); Amifostine (a protective medicine used during cancer treatment)

Concomitant treatment with an antacid: always take **NEBILET** with a meal and take the antacid between meals.

#### 4. HOW TO TAKE NEBILET:

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

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

##### ***If you have high blood pressure (adults only):***

The usual dose is 5 mg per day (or one tablet per day), with or without meals, preferably at the same time every day.

##### ***If you are also suffering from kidney impairment:***

The starting dose is half a tablet per day, with or without meals. Your doctor may increase the dose to one tablet per day.

##### ***If you are also suffering from liver impairment:***

Do not take **NEBILET**.

##### ***The elderly (if you are aged above 65 years):***

The recommended dose is half a tablet per day, or as directed by your doctor.

***If you are suffering from chronic heart failure (adults, including the elderly):***

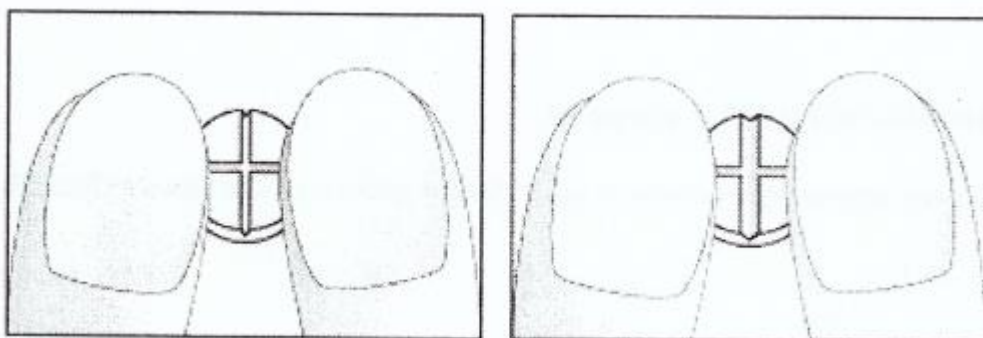
The initial dose is a quarter of a tablet once daily. However, your doctor will prescribe a suitable dose for you.

Do not take **NEBILET** if you also have liver impairment and/ or kidney impairment.

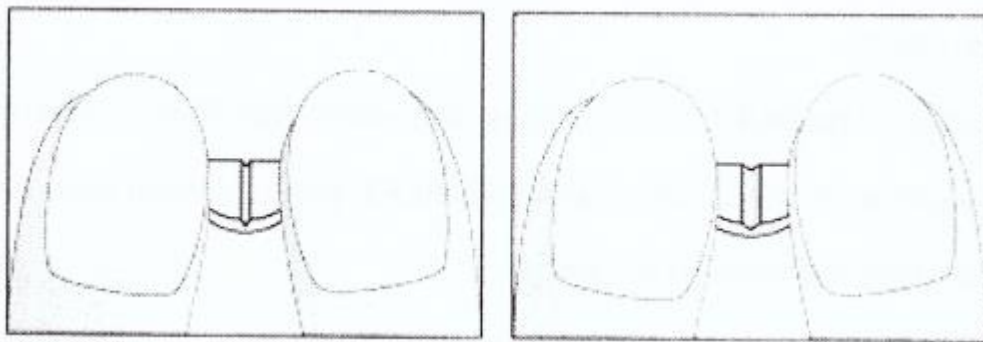
Your doctor will tell you how long your treatment with **NEBILET** will last. Do not stop treatment early because you may aggravate your heart problems. Seek advice from your doctor on how to discontinue **NEBILET** therapy.

**If you have been told by your doctor to take  $\frac{1}{4}$  (quarter) or  $\frac{1}{2}$  (half) tablet daily, please refer to the instructions below on how to break NEBILET cross-scored tablets.**

- Place the tablets onto a flat, hard surface (e.g. a table or worktop), with the cross score facing up.
- Break the tablet by pushing it with the index fingers of both hands placed along one breakmark (Diagrams 1 and 2).
- Tablet quarters are obtained by breaking the halves in the same way (Diagrams 3 and 4).



Diagrams 1 and 2: Easy breaking of the **NEBILET 5 mg** cross-scored tablet in half.



Diagrams 3 and 4: Easy breaking of half of the **NEBILET 5 mg** cross-scored tablet into quarters.

If you have the impression that the effect of **NEBILET** is too strong or too weak, tell your doctor or pharmacist.

**If you take more NEBILET than you should:**

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

The most frequent symptoms and signs of a **NEBILET** overdose are very slow heartbeat (bradycardia), low blood pressure with possible fainting (hypotension), breathlessness such as in asthma (bronchospasm), and acute heart failure.

**If you missed a dose of NEBILET:**

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

If you forget a dose of **NEBILET**, 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.

**Effects when treatment with NEBILET is stopped:**

Your heart condition may be aggravated, consult your doctor before discontinuing **NEBILET** treatment.

Do not give **NEBILET** to children.

## 5. POSSIBLE SIDE EFFECTS:

**NEBILET** can have side effects.

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

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

- Rash, which may be accompanied by fever or flu-like symptoms
- Itching
- Fainting
- Worsening of heart failure

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

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

- Breathing difficulties
- Feeling asthmatic or showing symptoms of bronchitis such as coughing and chest pain
- If your heartbeats are irregular or abnormal, too fast or too slow

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

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

- Dizziness
- Light headedness
- Headache
- Fatigue



- A feeling of pins and needles
- Swelling of the lower limbs
- Impaired vision
- Nightmares
- Depression
- Vomiting
- Bloating
- Constipation
- Flatulence or passing gas
- Nausea
- Indigestion
- Diarrhoea
- Impotence

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **6. STORING AND DISPOSING OF NEBILET:**

Store below at or 25 °C.

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

Return all unused medicines to your pharmacist.

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

**STORE ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN**

## **7. PRESENTATION OF NEBILET:**

Tablets are blister packed in PVC/Aluminium blister in pack sizes of 28's or 30's.

## **8. IDENTIFICATION OF NEBILET:**

An off-white, circular, biconvex tablet with one-sided dividing cross score.

**9. REGISTRATION NUMBER:**

34/7.1.3/0495

**10. NAME AND ADDRESS OF THE REGISTRATION HOLDER:**

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69,

Bryanston, 2021

**11. DATE OF PUBLICATION:**

01/11/2000