# Front Side

335 mm

310 mm

Grain Direction

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS** S3

**NEBIMAK 5**
Nebivolol hydrochloride equivalent to Nebivolol 5 mg
Contains Sugar (141.84 mg of lactose monohydrate)

**Read all of this leaflet carefully before you start taking NEBIMAK 5**
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist nurse or other health care provider.
- **NEBIMAK 5** 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.

**What is in this leaflet**

1. What **NEBIMAK 5** is and what it is used for
2. What you need to know before you take **NEBIMAK 5**
3. How to take **NEBIMAK 5**
4. Possible side effects
5. How to store **NEBIMAK 5**
6. Contents of the pack and other information


## 1. What NEBIMAK 5 is and what it is used for

**NEBIMAK 5** 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.
**NEBIMAK 5** is used to treat high blood pressure (or hypertension).
It is also used in the treatment of mild to moderate essential hypertension.

## 2. What you need to know before you take NEBIMAK 5

**Do not take NEBIMAK 5**
- If you are hypersensitive (allergic) to nebivolol hydrochloride or any of the other ingredients of **NEBIMAK 5**
- If you have impaired liver functioning.
- If you are pregnant or breastfeeding.
- If you have low blood pressure.
- If you have untreated phaeochromocytoma (hormone-secreting tumour that can occur in the adrenal glands)
- If 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
- If you have metabolic acidosis (A condition in which too much acid accumulates in the body.)
- If you have asthma
- You have serious circulation problems in the arms or legs
- If you are under verapamil therapy
- Do not give **NEBIMAK 5** to children as safety and efficacy have not been established.

**Warnings and precautions**
Take special care with **NEBIMAK 5**
There are certain conditions which you may have or which require special care before or while taking **NEBIMAK 5.**
**Cardiovascular:**
- Tell your doctor if you have untreated chronic heart failure because taking **NEBIMAK 5** may worsen your condition.

Tell your doctor if you develop:
- Poor circulation in the arms or legs, e.g. Raynaud's disease or syndrome, cramp-like pains when walking
- 1st degree heart block (a kind of light heart conduction disorder that affects heart rhythm)
- A type of chest pain due to spontaneously occurring heart cramp called Prinzmetal angina

Do not discontinue **NEBIMAK 5** 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.

**Anaesthesia:**
If you are already taking **NEBIMAK 5** and need to have surgery, inform your doctor before hand as you will have to stop treatment at least 24 hours before surgery.

**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: **NEBIMAK 5** 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 **NEBIMAK 5** can cause mild to severe cases of breathing difficulties.

**Other:**
Psoriasis, a skin condition distinguished by scaly pink patches, may be aggravated.
Take **NEBIMAK 5** with caution if you have or had psoriasis, also inform your doctor about it.
Inform your doctor if you are suffering from myasthenia gravis.
Tell your doctor if you are suffering from kidney disease as you may experience worsening of side effects.

**Use in children and adolescents**
The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore, **NEBIMAK 5** should not be used in this age group.

**Other medicines and NEBIMAK 5**
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Inform your doctor in particular if you are taking any of the following medicines:
- 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, 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 medicine); Amifostine (a protective medicine used during cancer treatment)

Taking **NEBIMAK 5** with an antacid: always take **NEBIMAK 5** with a meal and take the antacid between meals.

**NEBIMAK 5 with food and drink and alcohol:**
**NEBIMAK 5** may be taken with or without food. The tablet is best taken with some water.

**Pregnancy, breastfeeding and fertility**
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **NEBIMAK 5**.
- Do not take **NEBIMAK 5** while you are if you are pregnant or breastfeeding.

**Driving and using machines**
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.

**NEBIMAK 5** contains
**NEBIMAK 5** contains lactose as an ingredient.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **NEBIMAK 5**

## 3. How to take NEBIMAK 5

- Do not share medicines prescribed for you with any other person.
- Always take **NEBIMAK 5** 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 **NEBIMAK 5** is too strong or too weak talk to your doctor or pharmacist.

**If you take more NEBIMAK 5 than you should**
In the event of overdosage, 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 **NEBIMAK 5** 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 forget to take NEBIMAK 5**
Do not take a double dose to make up for forgotten individual doses.
If you forget a dose of **NEBIMAK 5**, 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 stop taking NEBIMAK 5**
Stopping treatment should have no negative effects. However, intense itching (pruritus) may occur if you stop taking **NEBIMAK 5**. The itching may resolve spontaneously or in some cases, the itching may be intense and may require treatment to be restarted.

## 4. Possible side effects

**NEBIMAK 5** can have side effects.
Not all side effects reported for **NEBIMAK 5** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **NEBIMAK 5**, please consult your doctor, pharmacist or other healthcare professional for advice.

**If any of the following happens, stop taking NEBIMAK 5 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 **NEBIMAK 5**. You may need urgent medical attention or hospitalization.

**Tell your doctor immediately or go to the 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**:
*Frequently occurring side effects:*
- Headache
- Dizziness
- A feeling of pins and needles
- Shortness of breath
- Constipation
- Nausea
- Diarrhoea
- Fatigue
- Swelling of the lower limbs

*Less frequently occurring side effects:*
- Nightmares
- Depression
- Light headedness
- Impaired vision
- Difficulty in breathing
- Vomiting
- Flatulence or passing gas
- Skin reactions itchy skin and rashes.
- Impotence

*Frequency of side effects not known:*
- Oedema (swelling of the ankles, feet and legs)
- Hypersensitivity (allergic reaction)
- Hallucinations
- confusion
- Sleep disturbances
- Numbness and tingling in the feet or hands
- Cramps
- Decreased tear production
- Blurred vision, soreness
- Heart failure
- Blood and lymphatic disorders
- tiredness

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

**Reporting of side effects**
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc-org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **NEBIMAK 5.**

## 5. How to store NEBIMAK 5

Store at or below 25 °C.
Keep the blisters in the carton until required for use.
KEEP OUT OF REACH OF CHILDREN

## 6. Contents of pack and other information

**What NEBIMAK 5 contains**
**NEBIMAK 5**: Each tablet contains nebivolol hydrochloride equivalent to nebivolol 5 mg.
**Other ingredients include:**
Corn starch / Maize starch, croscarmellose sodium, hydroxypropyl methyl cellulose, polysorbate 80, microcrystalline cellulose, colloidal silicon dioxide and magnesium stearate
Contains sugar: Lactose monohydrate (141.84 mg)

**What NEBIMAK 5 looks like and contents of the pack**
**NEBIMAK 5:**
White to off white, circular, biconvex uncoated tablets, debossed with "T 56" on one side and cross score line on the other side.
**Blister pack:**
Tablets are packed in a blister containing plain aluminium foil with heat seal lacquered as the lidding material and clear PVC/PVDC as the forming material. The blister is packed in an outer carton.
**Blister pack cold form**:
Tablets are packed in a blister containing plain aluminium foil with heat seal lacquered as the lidding material and cold form laminate as the forming material. The blister is packed in an outer carton.

Pack sizes include 10, 28 or 30 tablets.
Not all packs and pack sizes are necessarily marketed.

**Holder of Certificate of Registration and Manufacturer**
**MACLEODS PHARMACEUTICALS SA (PTY) LTD**
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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**Registration number**
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**Access to the corresponding Professional Information**
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

**NEBIMAK 5**
PM04342824

# Back Side

335 mm

310 mm

**PASIËNTINLIGTINGSTUK**

**SKEDULERINGSTATUS:** S3

**NEBIMAK 5**
Nebivololhidrochloried gelykstaande aan Nebivolol 5 mg
Bevat suiker (141,84 mg laktose monohidraat)

**Lees hierdie hele inligtingstuk noukeurig deur voordat jy NEBIMAK 5 begin neem**
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of jou apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **NEBIMAK 5** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

**Wat is in hierdie inligtingstuk**

1. Wat **NEBIMAK 5** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **NEBIMAK 5** neem
3. Hoe om **NEBIMAK 5** te neem
4. Moontlike newe-effekte
5. Hoe om **NEBIMAK 5** te bewaar
6. Inhoud van die pak en ander inligting


## 1. Wat NEBIMAK 5 is en waarvoor dit gebruik word

**NEBIMAK 5** behoort aan 'n groep van medisyne bekend as selektiewe beta-blokkerings middels wat selektief op die kardiovaskulêre stelsel werk. Hierdie medisyne werk deur bloeddruk te verlaag, verhoogde harttempo te verhoed en hartpompkrag te beheer. Dit oefen ook 'n verwydingsaksie op bloedvate uit, wat ook bydra om bloeddruk te verlaag.
**NEBIMAK 5** word gebruik om hoë bloeddruk (of hipertensie) te behandel.
Dit word ook gebruik in die behandeling van ligte tot matige noodsaaklike hipertensie.

## 2. Wat jy behoort te weet voordat jy NEBIMAK 5 neem

**Moet nie NEBIMAK 5 neem nie:**
- Indien jy hipersensitief (allergies) is vir nebivololhidrochloried of enige van die ander bestanddele van **NEBIMAK 5**
- Indien jy ingekorte lewerfunksie het.
- Indien jy swanger is of borsvoed.
- Indien jy lae bloeddruk het.
- Indien jy onbehandelde feochromositoom het (hormoon-afskeidende tumor wat in die byniere kan voorkom)
- Indien jy hartprobleme het soos baie stadige hartklop, onreëlmatige hartklop.
- Jy 'n onlangse hartversaking gehad, of verergering van 'n bestaande harttoestand het.
- Indien jy metaboliese asidose het ('n Toestand waarin te veel suur in die liggaam ophoop.)
- Indien jy asma het
- Jy ernstige sirkulasieprobleme in die arms of bene het.
- Indien jy onder verapamil behandeling is
- Moet nie **NEBIMAK 5** aan kinders gee nie, aangesien veiligheid en doeltreffendheid nie vasgestel is nie.

**Waarskuwings en voorsorgmaatreëls**
Neem spesiale sorg met **NEBIMAK 5**
Daar is sekere toestande wat jy mag hê of wat spesiale sorg vereis voor of tydens die neem van **NEBIMAK 5**.
**Kardiovaskulêre:**
- Vertel jou dokter indien jy onbehandelde chroniese hartversaking het, want die neem van **NEBIMAK 5** kan jou toestand vererger.

Vertel jou dokter as jy ontwikkel:
- Swak sirkulasie in die arms of bene, byvoorbeeld Raynaud se siekte of sindroom, krampagtige pyne wanneer jy loop
- 1ste graad hartblok ('n soort van ligte hartgeleidings versteuring wat hartritme affekteer)
- 'n Tipe borskaspyn, as gevolg van hartkramp wat spontaan voorkom, naamlik Prinzmetal angina

Moet nie die **NEBIMAK 5** behandeling skielik staak sonder om jou dokter te raadpleeg nie, jou dokter sal jou adviseer oor hoe jy die behandeling kan staak sonder om jou in gevaar te stel vir meer hartverwante probleme.

**Narkose:**
Indien jy alreeds **NEBIMAK 5** neem en 'n operasie moet ondergaan, moet jy jou dokter voor die tyd in kennis stel, aangesien jy die behandeling ten minste 24 uur voor die operasie sal moet stop.

**Metaboliese/endokrinologiese:**
Vertel jou dokter as jy die volgende metaboliese siektes het:
- Diabetes: waarskuwingstekens (abnormale of onreëlmatige hartklop) van lae bloedsuiker kan versteek word
- Ooraktiewe skildklier: **NEBIMAK 5** kan die tekens van 'n ooraktiewe skildklier versluier
- Skielike onttrekking kan simptome verskerp.

**Respiratories:**
Stel jou dokter in kennis indien jy aan asma, brongitis en ander chroniese respiratoriese siektes ly, aangesien behandeling met **NEBIMAK 5** ligte tot ernstige gevalle van asemhalingsprobleme kan veroorsaak.

**Ander:**
Psoriase, 'n veltoestand wat onderskei word deur skubberige pienk kolle, kan vererger word.
Neem **NEBIMAK 5** met versigtigheid indien jy psoriase het of gehad het, stel ook jou dokter daaroor in kennis.
Stel jou dokter in kennis indien jy aan miastenie gravis ly.
Vertel jou dokter as jy aan niersiekte ly, aangesien jy verergering van newe-effekte kan ervaar.

**Gebruik in kinders en adolessente**
Die veiligheid en doeltreffendheid in kinders en adolessente (onder 18 jarige ouderdom) is nie vasgestel nie en daarom moet **NEBIMAK 5** nie in hierdie ouderdomsgroep gebruik word nie.

**Ander medisyne en NEBIMAK 5**
Vertel altyd jou professionele gesondheidsorgwerker as jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Stel veral jou dokter in kennis indien jy enige van die volgende medisyne gebruik:
- Medisyne vir die beheer van die bloeddruk of medisyne vir hartprobleme (soos amiodaroon, amlodipien, sibensolien, klonidien, digoksien, diltiasem, disopiramied, felodipien, flekainied, guanfasien, hidro-kwinidien, lakidipien, lidokaien, metieldopa, meksiletien, moksonidien, nikardipien, nifedipien, nimodipien, nitrendipien, propafenoon, kwinidien, rilmenidien, verapamil).
- Kalmeermiddels en behandeling vir psigose ('n geestesongesteldheid) bv. barbiturate (ook gebruik vir epilepsie), fenotiasien (ook gebruik vir braking en naarheid) en tioridasien.
- Medisyne vir depressie bv. amitriptillien, paroksetien, fluoksetien.
- Medisyne wat gebruik word vir narkose tydens 'n operasie.
- Medisyne vir asma, geblokkeerde neus of sekere oogafwykings soos gloukoom (verhoogde druk in die oog) of dilatasie (verwyding) van die pupil.
- Baklofen ('n anti-spasmodiese medisyne); Amifostien ('n beskermende middel wat tydens kankerbehandeling gebruik word)

Neem **NEBIMAK 5** met 'n teensuurmiddel: neem altyd **NEBIMAK 5** met 'n maaltyd en neem die teensuurmiddel tussen maaltye.

**NEBIMAK 5 met voedsel en vloeistowwe en alkohol:**
**NEBIMAK 5** kan met, of sonder kos geneem word. Die tablet word die beste met bietjie water geneem.

**Swangerskap, borsvoeding en fertiliteit**
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **NEBIMAK 5** neem.
- Moet nie **NEBIMAK 5** neem terwyl jy swanger is of as jy borsvoed nie

**Bestuur en gebruik van masjinerie**
Jy kan newe-effekte soos duiseligheid en moegheid ervaar, wat jou vermoë om te bestuur en masjiene te gebruik, kan inkort. Moet nie bestuur of masjiene gebruik indien jy deur hierdie newe-effekte geaffekteer word nie.

**NEBIMAK 5** bevat
**NEBIMAK 5** bevat laktose as 'n bestanddeel.
Indien jy deur jou dokter meegedeel is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy **NEBIMAK 5** neem.

## 3. Hoe om NEBIMAK 5 te neem

- Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
- Neem altyd **NEBIMAK 5** presies soos wat jou dokter vir jou gesê het. Bevestig met jou dokter of apteker indien jy nie seker is nie.
- Indien jy die indruk kry dat die effek van **NEBIMAK 5** te sterk of te swak is, praat met jou dokter of apteker.

**Indien jy meer NEBIMAK 5 neem as wat jy moet**
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Die mees algemene simptome en tekens van 'n **NEBIMAK 5** oordosis is baie stadige hartklop (bradikardie), lae bloeddruk met moontlike floute (hipotensie), asemloosheid soos in asma (brongospasma) en akute hartversaking.

**Indien jy vergeet om NEBIMAK 5 te neem**
Moet nie 'n dubbel dosis neem om op te maak vir vergete individuele dosisse nie.
Indien jy 'n dosis van **NEBIMAK 5** vergeet, maar onthou 'n bietjie later dat jy dit moes geneem het, neem daardie dag se dosis soos gewoonlik. Indien 'n lang vertraging egter plaasgevind het (bv. 'n paar uur), sodat die volgende dosis naby is, slaan die vergete dosis oor en neem die volgende, geskeduleerde, normale dosis op die gewone tyd. Moet nie 'n dubbel dosis neem nie. Herhaalde oorslaan moet egter vermy word.

**Indien jy ophou om NEBIMAK 5 te neem**
Staak van behandeling behoort geen negatiewe effekte te hê nie. Intense gejeuk (pruritus) kan egter voorkom as jy ophou om **NEBIMAK 5** te neem. Die gejeuk kan spontaan opklaar, of in sommige gevalle kan die gejeuk intens wees en en kan vereis dat behandeling weer begin word.

## 4. Moontlike newe-effekte

**NEBIMAK 5** kan newe-effekte hê.
Nie alle newe-effekte wat vir **NEBIMAK 5** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid vererger of indien jy enige ongunstige effekte ervaar terwyl jy **NEBIMAK 5** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

**Indien enige van die volgende gebeur, hou op om NEBIMAK 5 te neem en kontak onmiddellik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal:**
- Uitslag, wat gepaard gaan met koors of griepagtige simptome
- Gejeuk
- Floute
- Verergering van hartversaking

Hierdie is alles baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige allergiese reaksie op **NEBIMAK 5** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.

**Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:**
- Asemhalingsprobleme
- Voel asmaties of toon simptome van brongitis, soos hoes en borskaspyn
- As jou hartklop onreëlmatig of abnormaal is, te vinnig of te stadig

Hierdie is alles ernstige newe-effekte. Jy benodig moontlik dringende mediese hulp.

**Lig jou dokter in indien jy enige van die volgende opmerk:**
*Newe-effekte wat dikwels voorkom:*
- Hoofpyn
- Duiseligheid
- 'n Gevoel van naalde en spelde
- Kort van asem
- Hardlywigheid
- Naarheid
- Diarree
- Moegheid
- Swelling van die onderste ledemate

*Newe-effekte wat minder gereeld voorkom:*
- Nagmerries
- Depressie
- Lighoofdigheid
- Verswakte visie
- Probleme met asemhaling
- Braking
- Winderigheid of winde passeer
- Velreaksies jeukende vel en uitslag.
- Impotensie

*Frekwensie van newe-effekte nie bekend nie:*
- Edeem (swelling van die enkels, voete en bene)
- Hipersensitiwiteit (allergiese reaksie)
- Hallusinasies
- verwarring
- Slaapstoornisse
- Gevoelloosheid en tinteling in die voete of hande
- Krampe
- Verminderde traanproduksie
- Dowwe visie, seerheid
- Hartversaking
- Bloed- en limfversteurings
- moegheid

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.

**Aanmelding van newe-effekte**
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en eReporting-platform (who-umc-org) wat op die SAHPRA-webwerf gevind word. Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **NEBIMAK 5**.

## 5. Hoe om NEBIMAK 5 te bewaar

Bewaar by of onder 25 °C.
Hou die stulpstrook in die karton totdat dit benodig word vir gebruik.
HOU BUITE BEREIK VAN KINDERS.

## 6. Inhoud van die pak en ander inligting

**Wat NEBIMAK 5 bevat**
**NEBIMAK 5** mg: Elke tablet bevat nebivololhidrochloried gelykstaande aan nebivolol 5 mg.
**Ander bestanddele sluit in:**
Mieliestysel, natriumkroskarmellose, hidroksipropiel metielsellulose, polisorbaat 80, mikrokristallyne sellulose, kolloïdale silikondioksied en magnesiumstearaat
Bevat suiker: Laktose monohidraat (141,84 mg)

**Hoe NEBIMAK 5 lyk en inhoud van die pak**
**NEBIMAK 5 mg:**
Wit tot naaswit, sirkelvormige, bikonvekse onbedekte tablette, bedruk met "T 56" aan die een kant en kruis keeplyn aan die ander kant.
**Stulpstrook pak:**
Tablette word verpak in 'n stulpstrook wat gewone aluminiumfoelie bevat met hitte seël gelak as die dekmateriaal en deursigtige PVC/PVDC as die vormingsmateriaal. Die stulpstrook is in 'n buitenste karton verpak.
**Stulpstrook pak koue vorm:**
Tablette word verpak in 'n stulpstrook wat gewone aluminiumfoelie bevat met hitte seël gelak as die dekmateriaal en koue vorm laminaat as die vormingsmateriaal. Die stulpstrook is in 'n buitenste karton verpak.
Verpakkingsgroottes sluit 10, 28 of 30 tablette in.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

**Houer van Sertifikaat van Registrasie en Vervaardiger**
**MACLEODS PHARMACEUTICALS SA (EDMS) BPK**
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
1 Cussonia-Rylaan, Bassonia Rock, Uitbr. 12,
Alberton, Suid-Afrika

**Hierdie inligtingstuk was laas hersien in**
02 Julie 2025

**Registrasienommer**
56/7.1.3/0393

**Toegang tot die ooreenstemmende Professionele Inligting**
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

PACKAGING RESEARCH & DEVELOPMENT

*Restricted Circulation*

(Front Page)

# ARTWORK / PRINTPROOF APPROVAL FORM

| | |
|---|---|
| **1. Product: NEBIMAK 5 (Nebivolol Tablets 5 mg )** | |
| **2. Country: South Africa (Private Market )** | **3. Packaging component: Patient Information Leaflet** |
| **4. No. of Colours: 1 Colour** | **5. Pantone Shade No.: Black** |
| **6. Specification: 40 gsm bible paper** | |
| **7. Machine Layout No.: NA** | **8. Dimensions: 335 (L) x 310 (W) mm** |
| **9. Design / Style: Booklet** | **10. Item code No.: PM04342824** |
| **11. Artwork has been made: Actual Size** | **12. Pharma code No.: 41320 mini** |
| **13. Barcode/NDC No: NA** | **14. Supersedes Item code No: NA** |
| **15. Revision no: 00** | **16. A/W File name:G:\Regulated_Artwork\SOUTH AFRICA\Nebivolol\Private Market\Nebivolol Tablets 5 mg PIL - PM04342824.cdr** |
| **Approved By:** | **17. Location: Baddi** |

| PRD | M.A. HOLDER | RAD | QC | PRODN | QA |
|---|---|---|---|---|---|
| | 26/05/2026 | | | | |

**Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.**

**Instructions to Vendor** :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.



| Reason for revision : | Item code | Artwork Send for Printing Date | Artwork Implementation Date |
|---|---|---|---|
| 1) New Artwork for South Africa (Private Market) | PM04342824 | | |