

## **Package leaflet: Information for the user**

### **Nebkliq 5 mg/5 mg film-coated tablets Nebkliq 5 mg/10 mg film-coated tablets nebivolol/amlodipine**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Nebkliq is and what it is used for**

Nebkliq contains two active substances called nebivolol and amlodipine. Both of these substances help to control your high blood pressure:

- nebivolol is 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 to lower blood pressure.
- amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening thereby reducing blood pressure.

Nebkliq is used to treat high blood pressure in adult patients who already receive nebivolol and amlodipine from separate tablets at the same doses.

#### **2. What you need to know before you take Nebkliq**

##### **Do not take Nebkliq if you:**

- are allergic to nebivolol, to amlodipine or a special group of calcium channel blockers, the dihydropyridines or to any of the other ingredients of this medicine (listed in section 6).
- have liver problems
- have heart failure, which has just occurred or which has recently become worse, or you are receiving treatment by intravenous drip feed for circulatory shock due to acute heart failure to help your heart work
- have certain serious heart rhythm problems (e.g. 2nd and 3rd degree atrioventricular block, heart conduction disorders)
- have asthma or wheezing (now or in the past)
- have untreated phaeochromocytoma, a tumour located in the adrenal glands, which are located on top of the kidneys
- have a metabolic disorder (metabolic acidosis)
- have very slow heartbeat (less than 60 beats per minute)

- have low or severe low blood pressure
- have serious circulation problems in the arms or legs
- have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body)
- suffer from heart failure after a heart attack.

Do not take Nebkqliq if any of the above apply to you. If you are not sure, talk to your doctor before taking Nebkqliq.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Nebkqliq

#### Tell your doctor if you:

- have abnormally slow heartbeat
- have a type of chest pain due to spontaneously occurring heart cramp which is called “Prinzmetal angina”
- have untreated chronic heart failure
- have 1st degree heart block (a kind of light heart conduction disorder that affects heart rhythm)
- have poor circulation in the arms or legs, e.g. Raynaud’s disease or syndrome, cramp-like pains when walking
- have prolonged breathing problems
- have 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) and could increase the risk of severe hypoglycaemia when used with certain type of antidiabetic drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)
- have overactive thyroid gland: this medicine may mask the signs of an abnormally fast heart rate due to this condition
- have allergy: this medicine may intensify your reaction to pollen or other substances you are allergic to
- psoriasis (a skin disease - scaly pink patches) or if you have ever had psoriasis
- have to have surgery, always inform your anaesthetist that you are taking Nebkqliq before being anaesthetized
- have had a recent heart attack
- have a recent heart failure or problems with your heart valves or heart muscle
- have severe increase in blood pressure (Hypertensive crisis)

As with any medicine which reduces blood pressure, an excessive drop in blood pressure in patients with blood flow disturbances of the heart or brain could lead to a heart attack or stroke. Your doctor will therefore check your blood pressure carefully.

See also information under the heading ‘Do not take Nebkqliq’

### **Children and adolescents**

Because of the lack of data on the use of the product in children and adolescents under the age of 18, Nebkqliq is not recommended for use in them.

### **Other medicines and Nebkqliq**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking:

- **Other blood pressure lowering medicines**, as the effect of Nebkqliq can be increased.
- **Amiodarone, cibenzoline, clonidine, digoxin, diltiazem, disopyramide, felodipine, flecainide, guanfacin, hydroquinidine, lacidipine, lidocaine, methyldopa, mexiletine, moxonidine, nicardipine, nifedipine, nimodipine, nitrendipine, propafenone, quinidine, rilmenidine, verapamil**, medicines for controlling the blood pressure or medicines for heart

problems.

- **Barbiturates** (a group of medicine used as sedative and therapy for psychosis, but also for epilepsy, anxiety, insomnia and seizure disorders), as the effect of Nebkqliq can be increased.
- **Phenothiazine** (a group of medicine used as sedative and therapy for psychosis, but also for vomiting and nausea), as the effect of Nebkqliq can be increased.
- **Thioridazine** (a group of medicine used as sedative and therapy for psychosis), as the effect of Nebkqliq can be increased.
- **Amitriptyline, paroxetine, fluoxetine**, medicines for depression, as the effect of Nebkqliq can be increased.
- 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 medicine used during cancer treatment)
- Medicines for diabetes such as **insulin or oral antidiabetic drugs**; Nebkqliq has no effect on blood sugar, but it could conceal the warning signs of a low sugar level (e.g. palpitations, fast heartbeat). However, the concomitant use of X with a group of medicines called sulfonylureas could increase the risk of severe hypoglycaemia (see also information under the heading “Warning and Precautions”).
- Medicines for treating excessive stomach acid or ulcers (antacid drug): you should take Nebkqliq during a meal and the antacid drug between meals
- **Ketoconazole, itraconazole** (anti-fungal medicines)
- **Ritonavir, indinavir, nelfinavir** (so called protease inhibitors used to treat HIV)
- **Rifampicin, erythromycin, clarithromycin** (antibiotics)
- **Hypericum perforatum** (St. John’s Wort)
- **Dantrolene** (infusion for severe body temperature abnormalities)
- **Tacrolimus, sirolimus, temsirolimus, and everolimus** (medicines used to alter the way your immune system works)
- **Simvastatin** (a cholesterol lowering medicine)
- **Cyclosporine** (an immunosuppressant)

### **Nebkqliq with food and drink and alcohol**

Nebkqliq can be taken with food or on an empty stomach.

Grapefruit juice and grapefruit should not be consumed by people who are taking Nebkqliq. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Nebkqliq.

Take care when drinking alcohol while you are taking Nebkqliq, as you may feel faint or dizzy. If this happens to you, do not drink any alcohol, including wine, beer or alcopop.

### **Pregnancy and breast-feeding**

#### **Pregnancy**

Since an adequate amount of clinical data relating to pregnant women is not available, Nebkqliq is not recommended in pregnancy. Nebkqliq can only be considered if no other safer options are available and after a careful individual assessment of the relationship risk/benefit from your doctor, so inform your doctor if you are pregnant, if you think you may be pregnant or are planning to have a baby. Don’t forget to ask your doctor for advice before taking this medicine.

In case of use during pregnancy, careful monitoring of the condition of the fetus and the newborn may be necessary.

#### **Breast-feeding**

If you are breast-feeding or about to start breast-feeding ask your doctor for advice before taking this medicine. Nebkqliq is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

### **Driving and using machines**

Nebkliq may affect your ability to drive or use machines. If the medicine makes you feel sick, dizzy or tired, or gives you a headache, do not drive or use machines and contact your doctor immediately.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘**sodium-free**’.

### **3. How to take Nebkliq**

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

The recommended dose is one tablet daily, preferably at the same time each day.

Nebkliq 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, without being chewed. Do not take Nebkliq with grapefruit juice.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

#### **If you take more Nebkliq than you should**

If you accidentally take an overdose of this medicine, tell your doctor or pharmacist immediately.

The most frequent symptoms and signs of overdose are low blood pressure with fainting (hypotension) with possible increased in heart rate (reflex tachycardia), very slow heart beat (bradycardia), breathlessness such as in asthma (bronchospasm), and acute heart failure.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

#### **If you forget to take Nebkliq**

If you forget a dose of Nebkliq, 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 to make up for a forgotten tablet. Repeated skipping, however, should be avoided.

#### **If you stop taking Nebkliq**

Always consult your doctor before stopping Nebkliq treatment.

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

### **4. Possible side effects**

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

**Consult your doctor immediately if you experience any of the following side effects after taking this medicine.**

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- Swelling of eyelids, face or lips
- Swelling of the tongue and throat which causes great difficulty breathing
- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions
- Heart attack, abnormal heart beat

- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell.

The following other side effects have been reported. If any of these cause you problems, you should contact your doctor.

**Other possible side effects with Nebkliq:**

**Very common side effects** (may affect more than 1 in 10 people):

- swollen hands or feet (oedema)

**Common side effects** (may affect up to 1 in 10 people):

- fatigue
- abdominal pain, nausea
- dizziness
- headache
- somnolence
- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- palpitations
- flushing
- altered bowel habits (including diarrhoea and constipation)
- indigestion
- ankle swelling
- muscle cramps
- weakness
- visual disturbances, double vision

**Uncommon side effects** (may affect up to 1 in 100 people):

- slow heartbeat or other heart complaints
- low blood pressure
- cramp-like leg pains on walking
- feelings of depression
- vomiting
- breathlessness such as in asthma, due to sudden cramps in the muscles around the airways (bronchospasm)
- nightmares
- sleeplessness
- mood changes (including anxiety)
- taste abnormalities
- numbness or tingling sensation in your limbs; loss of pain sensation
- fainting
- trembling
- ringing in the ears
- arrhythmia (including ventricular tachycardia and atrial fibrillation)
- heart failure
- cough
- sneezing/runny nose caused by inflammation of the lining of the nose
- dry mouth
- flatulence
- hair loss
- increased sweating
- itchy skin, red patches on skin, skin discolouration
- joint or muscle pain
- back pain
- inability to obtain or maintain an erection
- discomfort or enlargement of the breasts in men

- discomfort in passing urine, increased need to urinate at night, increased number of times of passing urine
- pain, feeling unwell
- weight decrease or increase

**Rare side effects** (may affect up to 1 in 1,000 people):

- confusion

**Very rare side effects** (may affect up to 1 in 10,000 people):

- decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding
- worsening of psoriasis (a skin disease - scaly pink patches)
- excess sugar in blood (hyperglycaemia)
- increased muscle tension
- a disorder of the nerves which can cause muscular weakness, tingling or numbness
- inflammation of blood vessels, often with skin rash
- abdominal bloating (gastritis)
- swelling of the gums
- abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests
- sensitivity to light

**Not known** (frequency cannot be estimated from the available data):

- trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Nebkliq

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Nebkliq contains

- The active substances are nebivolol (as nebivolol hydrochloride) and amlodipine (as amlodipine besilate).  
**Nebkliq 5 mg/5 mg:** each film-coated tablet contains 5 mg nebivolol (as nebivolol hydrochloride: 2.5 mg of d-nebivolol and 2.5 mg of l-nebivolol) and 5 mg amlodipine (as amlodipine besilate).  
**Nebkliq 5 mg/10 mg:** each film-coated tablet contains 5 mg nebivolol (as nebivolol hydrochloride: 2.5 mg of d-nebivolol and 2.5 mg of l-nebivolol) and 10 mg amlodipine (as amlodipine besilate).
- The other ingredients are:  
*Tablet core:* Cellulose microcrystalline, croscarmellose sodium, maize starch, hypromellose,

polysorbate 80, silica colloidal anhydrous, magnesium stearate.

*Film-coat:*

**Nebkqliq 5 mg/5 mg:** OPADRY® 02B220019 yellow (composed of: Hypromellose, Titanium dioxide, Macrogol 400, Iron oxide yellow (E172));

**Nebkqliq 5 mg/10 mg:** OPADRY® Y-1-7000 white (composed of: Hypromellose, Titanium dioxide, Macrogol 400).

**What Nebkqliq looks like and contents of the pack**

Nebkqliq 5 mg/5 mg film-coated tablets are yellow, oval.

Nebkqliq 5 mg/10 mg film-coated tablets are white, oval with one-sided break-mark.

Nebkqliq is available in PVC/PVDC-Al blister in packs containing 14, 28, 30, 56, 84, 90 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

MENARINI INTERNATIONAL O.L.S.A..

1, Avenue de la Gare, L-1611

Luxembourg.

**Manufacturer**

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Firenze

Italy

Or

Saneca Pharmaceuticals, a.s.

Nitrianska 100, 920 27

Hlohovec,

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**The medicinal product is authorised in the Member States of the EEA under the following name:**

Estonia, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, France, Greece, Hungary, Italy, Latvia, Luxembourg, Poland, Portugal, Romania, Slovenia, Slovak Republic, Spain: Nesyrgy

Austria, Ireland: Nebkqliq

Lithuania: Kliqqo

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