

## **Patient Information Leaflet**

### **Beta-Cardone® Tablets 40 mg, 80 mg and 200 mg**

#### **Sotalol hydrochloride**

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

#### **In this leaflet:**

1. What Beta-Cardone is for
2. Before you take Beta-Cardone
3. How to take Beta-Cardone
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#### **1. What Beta-Cardone is for**

Beta-Cardone belongs to a group of medicines called beta blockers.

Beta blockers help to control the rhythm of your heart.

Beta-Cardone is used to treat serious irregular heart beat problems called arrhythmias. It is important to make your heart beat regularly again, especially if you have angina, heart failure or have had a heart attack. Beta-Cardone can help prevent attacks of angina and reduce the risk of having a further heart attack. Beta-Cardone is also used to lower high blood pressure and reduce anxiety.

#### **2. Before you take Beta-Cardone**

Do not take Beta-Cardone if:

- You are allergic to sotalol hydrochloride or any of the other ingredients of Beta-Cardone (see section 6)
- You have ever had asthma or difficulty breathing. Do not take this medicine if you have a history of wheezing, blocked lungs (obstructive airway disease) or asthma as it may make your breathing worse.
- Your heart beat is very slow or weak (perhaps due to sick sinus syndrome, a long QT interval)
- You have a particular heart beat disturbance called Torsade de pointes or heart block
- You suffer from congestive heart failure or shock resulting from heart failure
- You get chest pain (angina) at rest
- You have low blood pressure
- You have a tumour near your kidneys (phaeochromocytoma)
- You have poor circulation (eg. Raynaud's disease)
- You had, or have kidney disease
- You have diabetes
- You suffer from a condition called metabolic acidosis
- You are a child.

If any of the above apply to you, do not take Beta-cardone, talk to your doctor or pharmacist.

**Check with your doctor before taking Beta-Cardone if:**

- Your ankles swell up or you have difficulty breathing
- You have been told that the lower chamber of the left side of your heart (left ventricle) is unable to pump blood effectively
- You suffer serious allergic reactions to anything
- You have ever had psoriasis (scaly skin caused by your skin cells being produced too quickly)
- You have disturbed salt and water balance which may give you persistent diarrhoea
- You have an over active thyroid
- You have a cough or a cold
- You are a heavy or regular drinker of alcohol
- You are going to hospital to have an operation or a general anaesthetic.

Take special care if you are diabetic since Beta-cardone may hide the usual warning signs that your blood sugar is low.

If any of the above apply to you talk to your doctor or pharmacist.

**Tell your doctor if you are taking any of the following medicines:**

- Any medicines for your heart or blood pressure including disopyramide, amiodarone, lignocaine, hydralazine, digoxin, guanethidine, methyldopa, clonidine, reserpine, verapamil, nifedipine or diltiazem, or water tablets (diuretics)
- Medicines for depression including tricyclic antidepressants and barbiturates
- Phenothiazines such as chlorpromazine used for schizophrenia
- Halofantrine for malaria
- Medicines for pain or arthritis such as aspirin
- Medicines for relief of asthma symptoms such as salbutamol
- Cimetidine for stomach ulcers
- Anti-histamines such as terfenadine or astemizole used to treat allergies
- Insulin or oral medicine for diabetes.
- Tubocarine, a relaxant used with general anaesthetics.
- Any other medicine, including medicines obtained without a prescription.

If any of the above apply to you talk to your doctor or pharmacist.

**Taking Beta-Cardone with food and drink**

Do not drink alcohol when taking Beta- Cardone as the effect of the medicine may be increased. This may affect your heart or blood pressure.

**Pregnancy and breast-feeding**

If you are pregnant, trying to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking Beta-Cardone. If you take these tablets close to giving birth, your doctor will monitor your new baby for 1 to 2 days.

**Driving and using machines**

Beta-Cardone may cause you to feel dizzy or tired. If this happens to you, do not drive or use machinery.

**Information on sugar intolerance**

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

**3. How to take Beta-Cardone**

Always take Beta-Cardone exactly as your doctor has told you.

**Important:**

**Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.**

Remember: Swallow each tablet (whole) with a drink of water. If you only have to take the tablets once a day, then take them first thing in the morning.

**Do not exceed the stated dose.**

**Do not suddenly stop taking this medicine even if you feel better unless your doctor tells you to - it could make your condition worse.**

**Adults**

It is likely that you will start with a low dose which your doctor will gradually increase. Your doctor may also check your progress.

The following doses are a guide only:

The usual starting dose is 80 mg taken as a single dose or divided into two 40 mg doses. The dose is adjusted every 2 to 3 days whilst checking your heart beat.

Most people need 160 – 320 mg a day in two divided doses.

**People with kidney disease**

If you have kidney disease your dose will be reduced. Your doctor will choose the dose that is right for you.

If you have any queries about the amount of medicine you have been prescribed, ask your doctor.

**Children**

This medicine is not suitable for children.

**If you take more Beta-Cardone than you should**

Do not take more Beta-Cardone than you should. If you accidentally take too much, immediately contact the nearest hospital casualty department or your doctor. Too much Beta-Cardone can seriously affect your heart rate, blood pressure or breathing.

**If you forget to take Beta-Cardone**

Do not take a double dose to make up for a missed dose. Take your next dose at the usual time.

**If you stop taking Beta-Cardone**

**Do not stop taking Beta-Cardone tablets without first talking to your doctor.**

**Stopping them suddenly could make your condition worse.**

If possible, the tablets should be stopped over 1 to 2 weeks as other medicines are taken instead. Your doctor will tell you how to stop taking Beta-Cardone.

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

**4. Possible side effects**

Like all medicines Beta-Cardone can cause side effects, although not everybody gets them.

**Seek immediate medical help if you have any of the following symptoms:**

- **An irregular or slow heart beat**
- **Breathlessness**
- **Chest pain**
- **Swollen ankles**
- **Feeling faint or fainting.**

**Other side effects:**

- Feeling sick or being sick
- Diarrhoea
- Upset stomach
- Indigestion
- Stomach pain
- Wind or cramps
- Dizziness
- Feeling weak or tired
- Light-headedness
- Headache
- Problems sleeping
- Tingling or numbness in the hands or feet
- Cold, pale or blue extremities
- An increase in existing leg pain on walking
- Anxiety

- Mood changes
- Depression
- Altered sex drive or impotence
- Problems with your eyesight, hearing or taste
- Fever
- Skin rashes including flare ups of psoriasis
- Dry eyes and conjunctivitis.

**Other side effects: Frequency- Not known (the frequency cannot be estimated from available data):**

- Hair loss
- Excessive sweating
- Abnormally low levels of thrombocytes, also known as platelets, in the blood.

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.

## **5. How to store Beta-Cardone**

Keep out of the reach and sight of children.

Do not use Beta-Cardone after the expiry date shown on the pack. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

## **6. Further information**

### **What Beta-Cardone contains**

There are three strengths of Beta-Cardone Tablets containing 40 mg, 80 mg and 200 mg of the active substance sotalol hydrochloride.

The other ingredients include lactose, starch maize, pregelatinised starch, talc and magnesium stearate.

- The 40 mg tablets also contain indigo carmine (E132) and quinoline yellow (E104).
- The 80mg tablets also contain cochineal (E124) which may cause allergic reactions.

### **What Beta-Cardone looks like**

Beta-Cardone is a tablet. The three strengths are colour-coded to help identify the strength.

- The 40 mg tablets are green with “Evans/BC4” marked on them.
- The 80 mg tablets are pink with “Evans/BC8” marked on them.
- The 200 mg tablets are white with “Evans/BC20” marked on them.

Beta-Cardone Tablets 40 mg and 80 mg are supplied in blister packs of 56 or plastic bottles of 100 or 500 tablets. The 200 mg tablets are supplied in a plastic container or bottle of 28, 30, 100 or 500 tablets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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This leaflet was last updated February 2026.

**If this leaflet is difficult to see or read or you would like it in a different format, please contact**

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