

# Cardene 20mg and 30mg capsules

## Nicardipine hydrochloride



**Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- This medicine has been prescribed for you. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet:

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

The name of your medicine is Cardene 20mg/30mg capsules. However, it will be referred to as Cardene capsules throughout the remainder of the leaflet.

### 1. What Cardene is and what it is used for

#### What are Cardene capsules

Cardene capsules contain the active ingredient nicardipine hydrochloride which belongs to the class of drugs called calcium channel blockers. These cause relaxation of the smooth muscle of the blood vessels causing these vessels to widen or dilate.

#### What Cardene capsules are used for

Your medicine is used for the treatment of mild to moderate high blood pressure (hypertension) and to help prevent attacks of chest pain diagnosed by your doctor as chronic stable angina. Chronic stable angina is a pattern of attacks of chest pain that are predictable and reproducible under certain conditions such as after exercise, stress or in cold weather. They are short in duration and can be relieved by rest or certain drugs.

### 2. What you need to know before you take Cardene

#### Do not take Cardene

- if you are **allergic** to **nicardipine**, **other dihydropyridines**, or **any of the other ingredients of this medicine** (listed in section 6)
- if you have had a **recent heart attack** (ie. within the last month)
- if you suffer from a condition called **severe aortic stenosis** which is narrowing of your aortic heart valve
- if your **chest pain is diagnosed by your doctor as unstable angina** (for example, if the pattern of attacks of chest pain changes and occurs without exertion, you should contact your doctor immediately)
- if you need **immediate relief of chest pain in a sudden or acute angina attack** (this situation should be treated with a different class of medicine)
- **to try to prevent the occurrence of future heart attacks** (if you have already had at least one heart attack)
- if you are **pregnant or breast-feeding** (see Pregnancy and breast-feeding section)

### Warnings and precautions

#### Talk to your doctor before taking Cardene if you:

- have a heart, liver or kidney disorder. Your doctor may decide you need a lower dose.
- have had a stroke
- are about to undergo an operation

If you experience sudden dizziness, light-headedness or palpitations during treatment with Cardene capsules, speak to your doctor immediately.

### Children and adolescents

Do not give this medicine to children or adolescents under 18 years of age.

### Other medicines and Cardene

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of either Cardene capsules or other medicines.

Especially tell your doctor if you are using any of the following medicines:

- **digoxin** (used to treat heart problems)
- **cimetidine** (used to treat digestive problems)
- **cyclosporine, tacrolimus or sirolimus** (used to control the body's immune system)
- **other blood pressure lowering drugs**
- **rifampicin** (used to treat certain types of infectious disease)
- **beta blockers** (used to treat different disorders including high blood pressure and heart problems)
- **diuretics** (water tablets)

### Cardene with food and drink

Cardene capsules must NOT be taken with grapefruit juice since it could interact and alter the effects of Cardene capsules.

### Pregnancy and breast-feeding

You should NOT take Cardene capsules if you are pregnant. You must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant. You should NOT breast-feed if you are taking Cardene capsules. Ask your doctor or pharmacist for advice before taking any medicine.

### Driving and using machines

Cardene capsules may cause dizziness. If you suffer from this do not drive or operate machinery.

### 3. How to take Cardene

Always take this medicine exactly as your doctor has told you to and do not stop treatment unless they tell you to do so. Check with your doctor, pharmacist or nurse if you are not sure. Do not change the prescribed dose of your medicine yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor.

The usual starting dose for treating mild to moderate high blood pressure (hypertension) and to help prevent attacks of chest pain (chronic stable angina) is 20 mg every 8 hours. The usual effective dose is 30 mg every 8 hours. Your doctor may vary your dose according to your symptoms and blood pressure, taking particular care if you are elderly. The label will tell you how much to take and how often. If you are not sure, ask your doctor, pharmacist or nurse. Do not take this medicine if you are under 18 years of age.

Capsules should be swallowed whole with a glass of water, preferably at the same time each day. Do not use grapefruit juice.

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

If you take too many capsules or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

#### **If you forget to take Cardene**

If you forget to take a dose, take another dose as soon as you remember, provided there are at least 3 hours until your next dose. If this is not possible, do not take the missed dose. Do not take a double dose to make up for a forgotten dose.

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

### 4. Possible side effects

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

In some patients, Cardene capsules may cause an attack of angina (chest pain) shortly after first starting to take the capsules. **If this happens to you, do not take any further doses and contact your doctor.**

In addition a few patients experience an increase in the severity or frequency of chest pain during treatment with Cardene capsules. **If this happens to you, you must inform your doctor as soon as possible.**

#### **Most frequent side effects**

- headache
- ankle swelling (oedema)
- heat sensation
- facial flushing
- sensation of a stronger heart beat (palpitations)
- nausea
- dizziness

#### **Other side effects include:**

- heart complaints, such as increased heart rate (tachycardia)
- stomach upsets
- vomiting
- pins and needles
- drowsiness
- shortness of breath
- medically unexplained symptoms thought to be the result of psychological factors
- sleeplessness

- rashes
- itching
- ringing in the ears
- difficulty in passing urine or passing more urine than usual
- depression
- increased bleeding or bruising more easily than usual
- impotence (loss of libido)
- serious allergic reaction which causes difficulty in breathing or dizziness
- changes in blood tests of how your liver is working

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Cardene

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 (EXP). The expiry date refers to the last day of that month.

Do not store above 25°C.

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 to protect the environment.

### 6. Contents of the pack and other information

#### **What Cardene capsules contain**

The active substance is nicardipine hydrochloride. Each capsule contains either 20 mg or 30 mg of nicardipine hydrochloride.

The other ingredients are pregelatinised starch and magnesium stearate. The capsule shell contains gelatin, indigotine E132 and titanium dioxide E171.

#### **What Cardene capsules look like and contents of the pack**

Cardene 20mg capsules are coloured blue and white and are printed in red ink with the strength and company logo. Cardene 30mg capsules are coloured blue and pale blue and are printed in red ink with the strength and company logo.

Both strengths of capsules are supplied in blister packs of 56.

#### **Marketing Authorisation Holder and Manufacturer**

##### **Marketing authorisation holder:**

Astellas Pharma Ltd.,  
SPACE, 68 Chertsey Road,  
Woking  
Surrey  
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UK.

##### **Manufacturer:**

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