

Cardene SR 30mg or 45mg capsules

Nicardipine hydrochloride

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Read all of this leaflet carefully before you start using this medicine. 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 your 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.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Cardene SR capsules are and what they are used for
2. Before you take Cardene SR capsules
3. How to take Cardene SR capsules
4. Possible side effects
5. How to store Cardene SR capsules
6. Further information

The name of your medicine is Cardene SR 30mg/45mg capsules. However, it will be referred to as Cardene SR capsules throughout the remainder of the leaflet

1. WHAT CARDENE SR CAPSULES ARE AND WHAT THEY ARE USED FOR

What are Cardene SR capsules

Cardene SR 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 SR capsules are used for

Your medicine is used for the treatment of mild to moderate high blood pressure (hypertension).

2. BEFORE YOU TAKE CARDENE SR CAPSULES

Do not take Cardene SR capsules

- if you are **allergic** (hypersensitive) to **nicardipine, other dihydropyridines, or any of the other ingredients of Cardene SR capsules** (see list in section 6 'Further information')
- 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
- **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)
- if you are **under 18 years of age**

Take special care with Cardene SR capsules (and speak to your doctor)

Make sure your doctor knows 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
- experience sudden dizziness, light-headedness or palpitations on treatment with Cardene SR capsules (speak to your doctor immediately if this happens).

Taking other medicines and Cardene SR

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription. This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of either Cardene SR 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)

Taking Cardene SR capsules with food and drink

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

Pregnancy and breast-feeding

You should NOT take these 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 these capsules. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of Cardene SR capsules

This product contains **lactose**. If you are **lactose intolerant**, contact your doctor or pharmacist before taking this product.

3. HOW TO TAKE CARDENE SR CAPSULES

Dosage

Always take your medicine exactly as your doctor tells you to and do not stop treatment unless they tell you to do

so. 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) is 30 mg every 12 hours. The usual effective dose is 45 mg every 12 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 or pharmacist. 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 SR capsules 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 SR capsules

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 missed dose.

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

4. POSSIBLE SIDE EFFECTS

This medicine sometimes causes side-effects. These are usually mild and tend to pass with time, but if they trouble you consult your doctor.

In some patients, Cardene SR 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 SR 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, pharmacist or nurse. This includes any possible 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CARDENE SR CAPSULES

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

Protect from light and moisture and do not store above 25 °C.

This medicine must not be used after the date (EXP) printed on the pack. Return any leftover medicine to your pharmacist. Only keep it if your doctor tells you to.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Cardene SR capsules contain

Cardene SR capsules contain the active ingredient nifedipine hydrochloride in a sustained release formulation. Cardene SR capsules come in two strengths. Each capsule contains either 30mg or 45mg of nifedipine hydrochloride.

The other ingredients are pregelatinised starch, maize starch, magnesium stearate, microcrystalline cellulose, lactose and methacrylic acid copolymer. The capsule shell contains gelatin and titanium dioxide E171 and the 45mg capsule shell also contains indigo carmine E132. Printing Ink containing Shellac (E904), Red Iron Oxide (E172), Propylene Glycol, Ammonia Solution, Potassium Hydroxide.

What Cardene SR capsules look like and contents of the pack

Cardene SR 30 mg capsules are coloured opaque white and are printed in red ink with the strength and company logo.

Cardene SR 45 mg capsules are coloured opaque blue and are printed in red ink with the strength and company logo.

Both strengths of capsules are available in packs of 56.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for Cardene SR capsules 30mg and 45mg are held by Astellas Pharma Ltd., 2000 Hillswood Drive, Chertsey, Surrey, KT16 0RS, UK.

Cardene SR capsules are made by 3M Healthcare Limited, Morley Street, Loughborough, Leicestershire, LE11 1EP, UK. The site where batch release takes place is Astellas Pharma Europe BV, Sylviusweg 62, 2333 BE Leiden, The Netherlands.

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