

INFORMATION FOR THE CONSUMER

IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT

PrCARDURA*

(doxazosin mesylate)

Benign Prostatic Hyperplasia

Please read this leaflet before you start taking CARDURA. Also read it each time you renew your prescription, in the event that something has changed. Remember that this leaflet does not replace careful discussions with your doctor.

WHY YOUR DOCTOR HAS PRESCRIBED CARDURA

Your doctor has prescribed CARDURA because you have a medical condition called benign prostatic hyperplasia or BPH. This condition occurs only in men. CARDURA can also be used to treat high blood pressure (hypertension), but this leaflet describes CARDURA only as a treatment for BPH.

WHAT IS BPH?

BPH is an enlargement of the prostate gland. After age 50, most men develop enlarged prostates. The prostate is located below the bladder and surrounds the urethra which is a tube that drains urine from the bladder. The symptoms of BPH, however, can be caused by an increase in the tightness of muscles in the prostate. If the muscles inside the prostate tighten, they can squeeze the urethra and slow the flow of urine. This can lead to symptoms such as:

- weak or interrupted urinary stream
- sensation that you cannot completely empty your bladder
- sensation of delay or hesitation when you start to urinate
- need to urinate often, especially at night, or
- sensation that you must urinate immediately.

Treatment Options for BPH

There are three main treatment options for BPH:

1. Monitoring Program or "Watchful Waiting"
If you have an enlarged prostate gland but suffer no symptoms or suffer from

symptoms that are not bothersome, you and your doctor may decide to follow a monitoring program which includes regular check-ups instead of medication or surgery.

2. Medication

There are different kinds of medication used to treat BPH. Your doctor has prescribed CARDURA for you. See "How does CARDURA work?", below.

3. Surgery

Some patients may require surgery. Your doctor can prescribe several different surgical procedures for BPH. The procedure which is best for you depends on your symptoms and medical condition.

HOW DOES CARDURA WORK?

CARDURA blocks smooth muscle receptors of the bladder neck and the prostate called alpha₁-adrenoceptors. This blockade causes the smooth muscles of the bladder neck and prostate to relax and decreases muscle tone. This can lead to a rapid improvement in urine flow and symptoms within 1 to 2 weeks period. However, not all patients respond in the same way, and since each case of BPH is different, you should keep in mind the following:

- Prior to treatment with CARDURA, you should have a thorough urological evaluation to determine the severity of your condition, and to exclude the need for immediate surgery or the possibility of carcinoma of the prostate.
- Even though taking CARDURA has helped your condition, it is not known whether CARDURA reduces the need for surgery.
- CARDURA will not cure your benign prostatic hyperplasia (BPH). CARDURA will make your urine flow better and improve the symptoms of BPH. In some patients, bothersome adverse effects may occur as a result of the CARDURA therapy.

WHAT YOU NEED TO KNOW WHILE TAKING CARDURA

- You should see an effect on your symptoms in 1 to 2 weeks. While taking CARDURA, you must have regular check-ups to evaluate your progress regarding your BPH and to monitor your blood pressure. Follow your doctor's advice about when to have these check-ups.
- CARDURA can cause a sudden drop in blood pressure after the very first dose. You may feel dizzy, faint, or "light-headed", particularly after you get up from bed or from a chair. This is more likely to occur after you have taken the first few doses, but can occur at any time while you are taking the drug. It can also occur if you stop taking the drug and then restart treatment. If you feel very dizzy, faint or "light-headed" you should contact your doctor. Your doctor will discuss with you how often you need to visit and how often your blood pressure should be checked.

- In general, you should be cautious when using a phosphodiesterase (PDE-5) inhibitor such as sildenafil, tadalafil or vardenafil when taking CARDURA due to the risks of developing serious hypotension (low blood pressure).

BEFORE you use CARDURA talk to your doctor or pharmacist if: you are using sildenafil, tadalafil or vardenafil.

- You can take CARDURA either in the morning or at bedtime and it will be equally effective. If you take CARDURA at bedtime but need to get up from bed to go to the bathroom, get up slowly and cautiously until you are sure how the medication affects you. It is important to get up slowly from a chair or bed at any time until you learn how you react to CARDURA. You should not drive or do any hazardous tasks until you are used to the effects of the medication. If you begin to feel dizzy, sit or lie down until you feel better.
- Other side effects you could have while taking CARDURA include drowsiness, fatigue (tiredness), swelling of the feet and shortness of breath. Most side effects are mild. Discuss any unexpected effects you notice with your doctor.
- Extremely rarely, CARDURA and similar medications have caused painful erection of the penis, sustained for hours and unrelieved by sexual intercourse or masturbation. This condition is serious, and if untreated it can be followed by permanent inability to have an erection. If you have a prolonged abnormal erection, call your doctor, or go to an emergency room as soon as possible.
- You may also experience dry or reduced or other kinds of ejaculation disorders, such as retrograde ejaculation. This condition may be harmless but can lead to temporary infertility during the medication usage.
- Your doctor has prescribed CARDURA for symptomatic BPH and not for prostatic cancer. It is possible for men to have both BPH and prostate cancer at the same time. Doctors usually recommend that men be checked for prostate cancer once a year when they turn 50 (or 40 if a family member has had prostate cancer). These checks should continue while you are taking CARDURA. CARDURA is not a treatment for prostate cancer.
- About Prostate Specific Antigen (PSA). Your doctor may have done a blood test called PSA. Your doctor is aware that CARDURA does not affect PSA levels. You may want to ask your doctor more about this if you have a PSA test done.

HOW TO TAKE CARDURA

Follow your doctor's instructions very carefully about how to take CARDURA.

You will start with a 1 mg dose of CARDURA once daily. Then the once daily dose will be increased as your body gets used to the effect of the medication. Follow your doctor's instructions about how to take CARDURA. You must take it every day at the dose

prescribed. Talk with your doctor if you don't take it for a few days for some reason; you may then need to restart the medication at a 1 mg dose, increase your dose gradually and again be cautious about possible dizziness. Do not share CARDURA with anyone else; it was prescribed only for you.

Notify your doctor about any illness which may develop during your treatment with CARDURA and about any new prescription or non-prescription medication you may take. If you require medical help for other reasons, inform the attending physician that you are taking CARDURA.

THIS MEDICINE IS PRESCRIBED FOR YOUR SPECIFIC MEDICAL PROBLEM AND FOR YOUR OWN USE. USE ONLY AS DIRECTED AND DO NOT GIVE TO OTHER PEOPLE.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN. FOR MORE INFORMATION ABOUT CARDURA AND BPH, TALK WITH YOUR DOCTOR OR PHARMACIST.

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