DOCUMENT INFORMATION PAGE

DARRTS COMMUNICATION

This page is for FDA internal use only. **Do NOT send this page with the letter.**

Application #(s):	NDA 19-668/S-022
CommunicationType:	Correspondence
Communication Group:	sNDA Action
Communication Name:	Approval
Communication ID:	COR-SNDAACTION-05
Drafted by:	Brum 1/12/10
Clearance History by:	Fromm 1/12/10; Southworth 1/12/10; Stockbridge 1/14/10
Finalized:	Brum 1/14/10
Filename:	
Notes:	**INSTRUCTION TO PM:** USE THIS LETTER (COR-SNDAACTION-05) FOR EFFICACY SUPPLEMENT AND NON-FDAAA LABELING SUPPLEMENT APPROVALS ONLY. USE COR-SNDAACTION-06 FOR sNDA CMC APPROVALS USE COR-SNDAACTION-09 FOR sNDA TENTATIVE APPROVALS USE COR-SNDAACTION-XX FOR sNDA FDAAA SAFETY LABELING CHANGES (Note: This letter is still under creation.)

Version: DARRTS 8/25/09, v.2

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-668/S-022 **SUPPLEMENT APPROVAL**

Pfizer, Inc.
Attention: Kathleen Collins
Manager, Worldwide Regulatory Strategy
235 East 42nd St.
New York, NY 10017

Dear Ms. Collins:

Please refer to your supplemental new drug application (NDA) dated October 29, 2009 and received October 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cardura (doxazosin mesylate) 1, 2, 4, and 8 mg Tablets.

We also acknowledge receipt of your submission dated January 11, 2010.

This "Changes Being Effected" supplemental new drug application was submitted to align the patient information leaflet (PIL) with certain safety information included in the package insert (USPI). This supplement provides for the following two additions to the PIL under the section "**How to Take CARDURA and What You Should Know While Taking CARDURA for BPH**":

- Tell your surgeon if you take or have taken CARDURA if you plan to have surgery for cataracts (clouding of the eye). During cataract surgery, a condition called Intraoperative Floppy Iris Syndrome (IFIS) can happen if you take or have taken CARDURA.

- If you use CARDURA with an oral erectile dysfunction medicine (phosphodiesterase-5 (PDE-5) inhibitor), it can cause a sudden drop in your blood pressure and you can become dizzy or faint. Talk with your healthcare provider before using PDE-5 inhibitors.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. For administrative purposes, please designate this submission, "**SPL for approved NDA 19-668/S-022**".

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Dan Brum, Pharm.D., RAC, Regulatory Project Manager, at (301)796-0578.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Agreed-upon labeling text

PATIENT INFORMATION ABOUT CARDURA®

Generic Name:
doxazosin mesylate
FOR BENIGN PROSTATIC HYPERPLASIA (BPH)

Read this leaflet:

- before you start taking CARDURA®
- each time you get a new prescription.

You and your doctor should discuss this treatment and your BPH symptoms before you start taking CARDURA and at your regular checkups. This leaflet does NOT take the place of discussions with your doctor.

CARDURA is used to treat both benign prostatic hyperplasia (BPH) and high blood pressure (hypertension). This leaflet describes CARDURA as treatment for BPH (although you may be taking CARDURA for both your BPH and high blood pressure).

What is BPH?

BPH is an enlargement of the prostate gland. This gland surrounds the tube that drains the urine from the bladder. The symptoms of BPH can be caused by a tensing of the enlarged muscle in the prostate gland which blocks the passage of urine. This can lead to such symptoms as:

- a weak or start-and-stop stream when urinating
- a feeling that the bladder is not completely emptied after urination
- a delay or difficulty in the beginning of urination
- a need to urinate often during the day and especially at night
- a feeling that you must urinate immediately

Treatment Options for BPH

The four main treatment options for BPH are:

- If you are not bothered by your symptoms, you and your doctor may decide on a program of "watchful waiting." It is not an active treatment like taking medication or surgery but involves having regular checkups to see if your condition is getting worse or causing problems.
- Treatment with CARDURA or other similar drugs. CARDURA is the medication your doctor has prescribed for you. See "What CARDURA Does," below.
- Treatment with the medication class of 5-alpha reductase inhibitors (e.g., Proscar®). It can cause the prostate to shrink. It may take 6 months or more for the full benefit of finasteride to be seen.
- Various surgical procedures. Your doctor can describe these procedures to you. The best procedure for you depends on your BPH symptoms and medical condition.

What CARDURA Does

CARDURA works on a specific type of muscle found in the prostate, causing it to relax. This in turn decreases the pressure within the prostate, thus improving the flow of urine and your symptoms.

- CARDURA helps relieve the symptoms of BPH (weak stream, start-and-stop stream, a feeling that your bladder is not completely empty, delay in beginning of urination, need to urinate often during the day and especially at night, and feeling that you must urinate immediately). It does not change the size of the prostate. The prostate may continue to grow; however, a larger prostate is not necessarily related to more symptoms or to worse symptoms. CARDURA can decrease your symptoms and improve urinary flow, without decreasing the size of the prostate.
- If CARDURA is helping you, you should notice an effect within 1 to 2 weeks after you start your medication. CARDURA has been studied in over 900 patients for up to 2 years and the drug has been shown to continue to work during long-term treatment. Even though you take CARDURA and it may help you, CARDURA may not prevent the need for surgery in the future.
- CARDURA does not affect PSA levels. PSA is the abbreviation for Prostate Specific Antigen. Your doctor may have done a blood test called PSA. You may want to ask your doctor more about this if you have had a PSA test done.

Other Important Facts

- You should see an improvement of your symptoms within 1 to 2 weeks. In addition to your other regular checkups you will need to continue seeing your doctor regularly to check your progress regarding your BPH and to monitor your blood pressure.
- CARDURA (doxazosin mesylate) is not a treatment for prostate cancer. Your doctor has prescribed CARDURA for your BPH and not for prostate cancer; however, a man can have 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). A higher incidence of prostate cancer has been noted in men of African-American descent. These checks should continue even if you are taking CARDURA.

How To Take CARDURA and What You Should Know While Taking CARDURA for BPH

CARDURA Can Cause a Sudden Drop in Blood Pressure After the VERY FIRST DOSE. You may feel dizzy, faint or "light-headed," especially after you stand up from a lying or sitting position. This is more likely to occur after you've taken the first few doses or if you increase your dose, 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.

Your blood pressure should be checked when you start taking CARDURA even if you do not have high blood pressure (hypertension). Your doctor will discuss with you the details of how blood pressure is measured.

Blood Pressure Measurement: Whatever equipment is used, it is usual for your blood pressure to be measured in the following way: measure your blood pressure after lying quietly on your back for five minutes. Then, after standing for two minutes measure your blood pressure again. Your doctor will discuss with you what other times during the day your blood pressure should be taken, such as two to six hours after a dose, before bedtime or after waking up in the morning. Note that moderate to high-intensity exercise can, over a period of time, lower your average blood pressure.

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.

- 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 effects 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.

- Other side effects you could have while taking CARDURA, in addition to lowering of the blood pressure, include dizziness, fatigue (tiredness), swelling of the feet and shortness of breath. Most side effects are mild. However, you should discuss any unexpected effects you notice with your doctor.
- **WARNING:** 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.
- Tell your surgeon if you take or have taken CARDURA if you plan to have surgery for cataracts (clouding of the eye). During cataract surgery, a condition called Intraoperative Floppy Iris Syndrome (IFIS) can happen if you take or have taken CARDURA.
- If you use CARDURA with an oral erectile dysfunction medicine (phosphodiesterase-5 (PDE-5) inhibitor), it can cause a sudden drop in your blood pressure and you can become dizzy or faint. Talk with your healthcare provider before using PDE-5 inhibitors.
- Keep CARDURA and all medicines out of the reach of children.

FOR MORE INFORMATION ABOUT CARDURA AND BPH TALK WITH YOUR DOCTOR, NURSE, PHARMACIST OR OTHER HEALTH CARE PROVIDER.

Distributed by

Roerig

Division of Pfizer Inc, NY, NY 10017

LAB-0070-3.0
Revised January 2010

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19668	SUPPL-22	PFIZER LABORATORIES DIV PFIZER INC	CARDURA

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY R SOUTHWORTH
01/14/2010