

PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

**PATIENT INFORMATION
CARVEDILOL PHOSPHATE
EXTENDED-RELEASE CAPSULES**

Read the Patient Information that comes with carvedilol phosphate extended-release capsules before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about carvedilol phosphate extended-release capsules, ask your doctor or pharmacist.

What is the most important information I should know about carvedilol phosphate extended-release capsules?

It is important for you to take your medicine every day as directed by your doctor. If you stop taking carvedilol phosphate extended-release capsules suddenly, you could have chest pain and a heart attack. If your doctor decides that you should stop taking carvedilol phosphate extended-release capsules, your doctor may slowly lower your dose over time before stopping it completely.

What are carvedilol phosphate extended-release capsules?

Carvedilol phosphate extended-release capsules are a prescription medicine that belongs to a group of medicines called “beta-blockers”. Carvedilol phosphate extended-release capsules are used, often with other medicines, for the following condition:

- to treat patients with high blood pressure (hypertension)

Carvedilol phosphate extended-release capsules are not approved for use in children under 18 years of age.

Who should not take carvedilol phosphate extended-release capsules?

Do not take carvedilol phosphate extended-release capsules if you:

- have severe heart failure and require certain intravenous medicines that help support circulation.
- have asthma or other breathing problems.
- have a slow heartbeat or certain conditions that cause your heart to skip a beat (irregular heartbeat).
- have liver problems.
- are allergic to any of the ingredients in carvedilol phosphate extended-release capsules. *See “What are the ingredients in carvedilol phosphate extended-release capsules?”*

The 20 mg strength of this drug product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

What should I tell my doctor before taking carvedilol phosphate extended-release capsules?

Tell your doctor about all of your medical conditions, including if you:

- have asthma or other lung problems (such as bronchitis or emphysema).
- have problems with blood flow in your feet and legs (peripheral vascular disease). Carvedilol phosphate extended-release capsules can make some of your symptoms worse.
- have diabetes.
- have thyroid problems.
- have a condition called pheochromocytoma.
- have had severe allergic reactions.
- are scheduled for surgery and will be given anesthetic agents.
- are scheduled for cataract surgery and have taken or are currently taking carvedilol phosphate extended-release capsules.
- are pregnant or trying to become pregnant. It is not known if carvedilol phosphate extended-release capsules are safe for your unborn baby. You and your doctor should talk about the best way to control your high blood pressure during pregnancy.
- are breastfeeding. It is not known if carvedilol phosphate extended-release capsules pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking carvedilol phosphate extended-release capsules.

Tell your doctor about all of the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements. Carvedilol phosphate extended-release capsules and certain other medicines can affect each other and cause serious side effects. Carvedilol phosphate extended-release capsules may affect the way other medicines work. Also, other medicines may affect how well carvedilol phosphate extended-release capsules work.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist before you start a new medicine.

How should I take carvedilol phosphate extended-release capsules?

- Take carvedilol phosphate extended-release capsules exactly as prescribed. Take carvedilol phosphate extended-release capsules **one** time each day with food. **It is important that you take carvedilol phosphate extended-release capsules only one time each day.** To lessen possible side effects, your doctor might begin with a low dose and then slowly increase the dose.
- Swallow carvedilol phosphate extended-release capsules whole. Do not chew or crush carvedilol phosphate extended-release capsules.
- If you have trouble swallowing carvedilol phosphate extended-release capsules whole:
 - The capsule may be carefully opened and the contents sprinkled over a spoonful of applesauce which should be eaten right away. The applesauce should not be warm.
 - Do not sprinkle contents on foods other than applesauce.
- **Do not stop taking carvedilol phosphate extended-release capsules and do not change the amount of carvedilol phosphate extended-release capsules you take without talking to your doctor.**
- If you miss a dose of carvedilol phosphate extended-release capsules, take your dose as soon as you remember, unless it is time to take your next dose. Take your next dose at the usual time. Do not take 2 doses at the same time.
- If you take too much carvedilol phosphate extended-release capsules, call your doctor or poison control center right away.

What should I avoid while taking carvedilol phosphate extended-release capsules?

Carvedilol phosphate extended-release capsules can cause you to feel dizzy, tired, or faint. Do not drive a car, use machinery, or do anything that needs you to be alert if you have these symptoms.

What are possible side effects of carvedilol phosphate extended-release capsules?

Serious side effects of carvedilol phosphate extended-release capsules include:

- **chest pain and heart attack if you suddenly stop taking carvedilol phosphate extended-release capsules.** *See “What is the most important information I should know about carvedilol phosphate extended-release capsules?”*
- **slow heart beat.**
- **low blood pressure (which may cause dizziness or fainting when you stand up).** If these happen, sit or lie down, and tell your doctor right away.
- **worsening heart failure.** Tell your doctor right away if you have signs and symptoms that your heart failure may be worse, such as weight gain or increased shortness of breath.
- **changes in your blood sugar. If you have diabetes, tell your doctor if you have any changes in your blood sugar levels.**
- masking (hiding) the symptoms of low blood sugar, especially a fast heartbeat.
- **new or worsening symptoms of peripheral vascular disease.**
 - leg pain that happens when you walk, but goes away when you rest
 - no feeling (numbness) in your legs or feet while you are resting
 - cold legs or feet
- masking the symptoms of hyperthyroidism (overactive thyroid), such as a fast heartbeat.
- **worsening of severe allergic reactions.** Medicines to treat a severe allergic reaction may not work as well while you are taking carvedilol phosphate extended-release capsules.
- **rare but serious allergic reactions** (including hives or swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing) have happened in patients who were on carvedilol tablets or carvedilol phosphate extended-release capsules. These reactions can be life-threatening. In some cases, these reactions happened in patients who had been on carvedilol tablets before taking carvedilol phosphate extended-release capsules.

Common side effects of carvedilol phosphate extended-release capsules include shortness of breath, weight gain, diarrhea, and tiredness. If you wear contact lenses, you may have fewer tears or dry eyes that can become bothersome.

Call your doctor if you have any side effects that bother you or don't go away.

Call your doctor for medical advice about side effects. **You may report side effects to FDA at 1-800-FDA-1088.**

How should I store carvedilol phosphate extended-release capsules?

Store carvedilol phosphate extended-release capsules at 20° to 25°C (68° to 77°F).

Safely throw away carvedilol phosphate extended-release capsules that are out of date or no longer needed.

Keep carvedilol phosphate extended-release capsules and all medicines out of the reach of children.

General information about carvedilol phosphate extended-release capsules

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use carvedilol phosphate extended-release capsules for a condition for which it was not prescribed. Do not give carvedilol phosphate extended-release capsules to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about carvedilol phosphate extended-release capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about carvedilol phosphate extended-release capsules that is written for healthcare professionals. Please address medical inquiries to 1-800-406-7984.

What are the ingredients in carvedilol phosphate extended-release capsules?

Active ingredient: carvedilol phosphate

Inactive ingredients: crospovidone, hypromellose, lactose mono-hydrate, magnesium stearate, methacrylic acid ethyl acrylate, methacrylic acid methyl methacrylate, microcrystalline cellulose, polyethylene glycol, propylene glycol, silicon dioxide, talc and triethyl citrate. The capsule shell contains gelatin and titanium dioxide. The 20 mg capsule shell also contains FD&C blue #1, FD&C yellow #5 and FD&C yellow #6. The 40 mg capsule shell also contains D&C yellow #10 and FD&C yellow #6. The 80 mg capsule shell also contains D&C yellow #10 and FD&C blue #1. The imprinting ink for the 10 mg, 40 mg and 80 mg contains D&C yellow #10 lake, FD&C blue #1, FD&C blue #2, FD&C red #40, iron oxide black, propylene glycol and shellac glaze. The imprinting ink for the 20 mg contains ammonium hydroxide, propylene glycol, shellac glaze, simethicone and titanium dioxide. Carvedilol phosphate extended-release capsules come in the following strengths: 10 mg, 20 mg, 40 mg, 80 mg.

What is high blood pressure (hypertension)?

Blood pressure is the force of blood in your blood vessels when your heart beats and when your heart rests. You have high blood pressure when the force is too much. High blood pressure makes the heart work harder to pump blood through the body and causes damage to blood vessels. Carvedilol phosphate extended-release capsules can help your blood vessels relax so your blood pressure is lower. Medicines that lower blood pressure may lower your chance of having a stroke or heart attack.

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