



150025961

## 17.2 FDA-Approved Patient Labeling

### PATIENT INFORMATION CARVEDILOL TABLETS USP

Read the Patient Information that comes with carvedilol tablets 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 tablets, ask your doctor or pharmacist.

#### What is carvedilol?

Carvedilol is a prescription medicine that belongs to a group of medicines called "beta-blockers". Carvedilol is used, often with other medicines, for the following conditions:

- To treat patients with high blood pressure (hypertension)
- To treat patients who had a heart attack that worsened how well the heart pumps

Carvedilol tablets are not approved for use in children under 18 years of age.

#### Who should not take carvedilol tablets?

Do not take carvedilol tablets if you:

- Have severe heart failure and are hospitalized in the intensive care unit or require certain intravenous medications that help support circulation (inotropic medications)
- Are prone to asthma or other breathing problems
- Have a slow heartbeat or a heart that skips a beat (irregular heartbeat)
- Have liver problems
- Are allergic to any of the ingredients in carvedilol tablets. The active ingredient is carvedilol. See the end of this leaflet for a list of all the ingredients in carvedilol tablets.

#### What should I tell my doctor before taking carvedilol tablets?

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 tablets can make some of your symptoms worse.

- Have diabetes
- Have thyroid problems
- Have a condition called pheochromocytoma
- Have had severe allergic reactions
- Are pregnant or trying to become pregnant. It is not known if carvedilol tablets 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 tablets passes into your breast milk. You should not breastfeed while using carvedilol tablets.
- Are scheduled for surgery and will be given anesthetic agents
- Are taking prescription or non-prescription medicines, vitamins, and herbal supplements. Carvedilol tablets and certain other medicines can affect each other and cause serious side effects. Carvedilol tablets may affect the way other medicines work. Also, other medicines may affect how well carvedilol tablet works

Keep a list of all the medicines you take. Show this list to your doctor and pharmacist before you start a new medicine.

#### How should I take carvedilol tablets?

**It is important for you to take your medicine every day as directed by your doctor. If you stop taking carvedilol tablets suddenly, you could have chest pain and/or a heart attack. If your doctor decides that you should stop taking carvedilol tablets, your doctor may slowly lower your dose over a period of time before stopping it completely.**

- Take carvedilol tablets exactly as prescribed. Your doctor will tell you how many tablets to take and how often. In order to minimize possible side effects, your doctor might begin with a low dose and then slowly increase the dose.
- **Do not stop taking carvedilol tablets and do not change the amount of carvedilol tablets you take without talking to your doctor.**
- Tell your doctor if you gain weight or have trouble breathing while taking carvedilol tablets.

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TEMPLE Packaging Pvt. Ltd. 28476001 Email:-temple@bom4.vsnl.net.in

Customer: Dr. Reddy's Location: Hyderabad

Product Code & Name: 150025961 Carvedilol Tab Med Guide (Insert-Front)

SAP Code: xxxxxxxxxxxx File No: xxxxx

Version No.: 2 Date: 19.03.2010

Open Size: 180 X 630 mm

Folding Size: 60 x 90 mm Pharma code: xxx

Colours: 1 (Black) Perforation: Yes

Substrate: 40 gsm Bible Gluing: No

Artwork Sr. No.: xxx

Artwork Status: in process

Note - This approval will be considered for final printing.

Please recheck for corrections indicated earlier, in this proof also.

Prepared by : Checked by: Approved by:

shaji

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- If you miss a dose of carvedilol tablets, 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 tablets, call your doctor or poison control center right away.

**What should I avoid while taking carvedilol tablets?**

Carvedilol tablets 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 tablets?**

- **Low blood pressure (which may cause dizziness or fainting when you stand up).** If these happen, sit or lie down right away and tell your doctor.
- **Tiredness.** If you feel tired or dizzy you should not drive, use machinery, or do anything that needs you to be alert.
- **Slow heart beat.**
- **Changes in your blood sugar. If you have diabetes, tell your doctor if you have any changes in your blood sugar levels.**
- Carvedilol tablets may hide some of the symptoms of low blood sugar, especially a fast heartbeat.
- Carvedilol tablets may mask the symptoms of hyperthyroidism (overactive thyroid).
- **Worsening of severe allergic reactions.**
- Rare but serious allergic reactions (including hives or swelling of the face, lips, tongue and/or throat that may cause difficulty breathing or swallowing) have happened in patients who were on carvedilol tablets. These reactions can be life-threatening.

Other side effects of carvedilol tablets include shortness of breath, weight gain, diarrhea, and fewer tears or dry eyes that become bothersome if you wear contact lenses.

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

**How should I store carvedilol tablets?**

- Store carvedilol tablets at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. Keep the tablets dry.

- Safely, throw away carvedilol tablets that is out of date or no longer needed.
- Keep carvedilol tablets and all medicines out of the reach of children.

**General Information About Carvedilol Tablets**

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use carvedilol tablets for a condition for which it was not prescribed. Do not give carvedilol tablets 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 tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about carvedilol tablets that is written for healthcare professionals. You can also find out more about carvedilol tablets by calling 1-888-375-3784. This call is free.

**What are the ingredients in carvedilol?**

Active Ingredient: Carvedilol USP

Inactive Ingredients: colloidal silicon dioxide, crospovidone, hypromellose 2910-5cP, lactose monohydrate, magnesium stearate, polyethylene glycol 400, polysorbate 80, povidone, synthetic yellow iron oxide and titanium dioxide.

Carvedilol tablets USP come in the following strengths: 3.125 mg, 6.25 mg, 12.5 mg, 25 mg

To reorder additional Patient Information Sheets contact Dr. Reddy's Customer Service at 1-866-733-3952.

R<sub>x</sub> only

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**Dr.Reddy's Laboratories Limited**  
Bachepalli – 502 325 INDIA

Revised: 0310



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<b>Customer:</b> Dr. Reddy's	<b>Location:</b> Hyderabad
<b>Product Code &amp; Name:</b> 150025961 Carvedilol Tab Med Guide (Insert-Back)	
<b>SAP Code:</b> xxxxxxxxxxxx	<b>File No:</b> xxxxx
<b>Version No.:</b> 2	<b>Date:</b> 19.03.2010
<b>Open Size:</b> 180 X 630 mm	
<b>Folding Size:</b> 60 x 90 mm	<b>Pharma code:</b> xxx
<b>Colours:</b> 1 (Black)	<b>Perforation:</b> Yes
<b>Substrate:</b> 40 gsm Bible	<b>Gluing:</b> No
<b>Artwork Sr. No.:</b> xxx	
<b>Artwork Status:</b> in process	
Note - This approval will be considered for final printing. Please recheck for corrections indicated earlier, in this proof also.	
Prepared by : shaji	Checked by: Approved by:

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