

## FDA-Approved Patient Labeling

### Patient Information

Olmesartan Medoxomil, Amlodipine and Hydrochlorothiazide (OL-me-SAR-tan me-DOX-oh-mil, am-LOE-di-peen and HYE-droe-KLOR-oh-THYE-a-zide) Tablets

Read the Patient Information that comes with Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets before you take them and each time you get a refill. There may be a new information. This leaflet does not take the place of talking with your doctor about your medical condition or treatment.

### **What is the most important information I should know about olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?**

- Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets can cause harm or death to an unborn baby.
- Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant.
- If you get pregnant while taking olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets, tell your doctor right away.

### **What are olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?**

Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets are a prescription medicine used to lower blood pressure (hypertension). Medicines that lower blood pressure lower your chance of having a stroke or heart attack. Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets are not for use as the first medicine to treat your high blood pressure.

Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets contain 3 different prescription medications:

1. amlodipine, a calcium channel blocker
2. olmesartan medoxomil, an angiotensin receptor blocker, and
3. hydrochlorothiazide, a diuretic (water pill)

It is not known if olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets are safe and work in children.

### **Who should not take olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?**

Do not take olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets if you:

- have low or no urine output
- are allergic to other Sulfonamide type medicines. Ask your doctor if you are not sure.
- are taking aliskiren and have diabetes.

### **What should I tell my doctor before taking olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?**

Before taking olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets, tell your doctor if you:

- **are pregnant or plan to become pregnant.** See “**What is the most important information I should know about olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?**”
- **are breast feeding or plan to breast feed.** One of the medicines in olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets can pass into your breast milk and may harm your baby. You and your doctor should decide if you will take olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets or breastfeed. You should not do both.
- Are allergic to any of the ingredients in olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets. See the end of the leaflet for a list of the ingredients in olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets.
- have liver problems
- have heart problems
- have kidney problems
- have lupus
- are vomiting or have a lot of diarrhea
- have any other medical conditions

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some of your other medicines and olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets could affect each other, causing serious side effects.

Especially tell your doctor if you are taking:

- water pills (diuretics)
- other medicines for high blood pressure or a heart problem
- potassium supplements or using salt substitute containing potassium
- diabetes medicine including insulin
- narcotic pain medicine
- sleeping pills and anti-seizure medicines called barbiturates
- lithium, a medicine used to treat certain kinds of depression
- medicines used to treat pain or arthritis such as aspirin or non-steroidal anti-inflammatory drugs (NSAIDs)
- steroids
- cholesterol lowering medicines
- tacrolimus and cyclosporine (medicines used to alter the way your immune system works)

Know the medicines you take. Keep a list of your medicines and show it to your doctor or pharmacist when you get a new medicine.

#### **How should I take olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?**

- Take olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets exactly as prescribed by your doctor. Your doctor may change your dose if needed.
- Take olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets one time a day.

- Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets can be taken with or without food.
- If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Just take the next dose at your regular time.
- If you take too much olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets, call your doctor or Poison Control Center, or go to the nearest hospital emergency room.

**What should I avoid while taking olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?**

**Drinking alcohol.** Drinking alcohol during treatment with olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets can cause you to have low blood pressure. See “What are the possible side effects of olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?”

**What are the possible side effects of olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?**

Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets may cause serious side effects, including:

- **Harm to an unborn baby causing injury or death.** See “What is the most important information I should know about olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?”
- **Low Blood Pressure (hypotension).** Low blood pressure may cause you to feel faint or dizzy. Lie down, if you feel faint or dizzy. Call your doctor right away.
- **Kidney problems.** Kidney problems may get worse in people that already have kidney disease. Blood tests for kidney function may be done while you are taking olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets and the doctor may need to lower your dose of olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets. Call your doctor if you get swelling in your feet, ankles, or hands, or unexplained weight gain. If you have heart failure, your doctor should check your kidney function before prescribing olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets.
- **Worsening chest pain or heart attack.** Get medical help right away if you have chest pain that gets worse, or that does not go away, during treatment with olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets.
- **Allergic reactions.** Hydrochlorothiazide, one of the medicines in olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets can cause allergic reactions.
- **Changes in body salts (such as sodium and potassium), and body fluids.** Tell your doctor if you have any of these signs or symptoms during treatment with olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets:
  - Dry mouth
  - thirst
  - weakness
  - tiredness or sleepiness
  - restless
  - confusion
  - seizures
  - muscle pains or cramps
  - muscle tiredness

- dizziness or fainting
- low or no urine output
- fast heartbeat
- nausea and vomiting
- **Eye problems.** One of the medicines in olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets can cause eye problems that may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets. Tell your doctor right away if you have:
  - decrease in vision
  - eye pain
- **Severe diarrhea and weight loss.** Severe, chronic diarrhea with considerable weight loss may develop months to years after starting olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets. Tell your doctor if you are experiencing these symptoms.

The most common side effects of olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets used to treat people with high blood pressure include:

- dizziness
- swelling (edema) of the ankles, feet, and hands
- headache
- tiredness
- stuffy or runny nose and sore throat
- muscle twitching (spasms)
- nausea
- upper respiratory tract infection
- diarrhea
- urinary tract infection
- swelling (edema) of the joints

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets. For more information, ask your doctor or pharmacist.

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

#### **How do I store olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?**

- Store olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets at 20° to 25°C (68° to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].
- **Keep olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets and all medicines out of the reach of children.**

#### **General Information about Olmesartan Medoxomil, Amlodipine and Hydrochlorothiazide Tablets**

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets for a

condition for which it was not prescribed. Do not give olmesartan medoxomil, amlodipine and hydrochlorothiazide 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 olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets that is written for health professionals. For more information call Torrent Pharma Inc. at 1-800-912-9561.

**What are the ingredients in olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets?**

*Active ingredients:* olmesartan medoxomil USP, amlodipine besylate USP, and hydrochlorothiazide USP.

*Inactive ingredients:* colloidal silicone dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, maize starch, pregelatinized maize starch, silicified microcrystalline cellulose, and talc.

The color coating material contains the following ingredients.

<b>Strength</b>	<b>Ingredients</b>
40/10/12.5 mg and 40/10/25 mg	Polyvinyl alcohol, titanium dioxide, polyethylene glycol/macrogol, talc, iron oxide yellow and iron oxide red
20/5/12.5 mg	Polyvinyl alcohol, titanium dioxide, polyethylene glycol/macrogol, talc, iron oxide yellow, iron oxide red and iron oxide black
40/5/12.5 mg and 40/5/25 mg	Polyvinyl alcohol, titanium dioxide, polyethylene glycol/macrogol, talc and iron oxide yellow

**What is high blood pressure (hypotension)?**

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. Olmesartan medoxomil, amlodipine and hydrochlorothiazide tablets can help your blood vessels relax so your blood pressure is lower.

This Patient Information has been approved by the U.S. Food and Drug Administration.



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