

Patient Information
EDARBYCLOR (eh-DAR-bih-clor)
(azilsartan medoxomil and chlorthalidone)
tablets

Read this Patient Information leaflet before you start taking Edarbyclor and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about Edarbyclor?

- Edarbyclor can cause harm or death to your unborn baby.
- Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant.
- If you become pregnant while taking Edarbyclor, tell your doctor right away. Your doctor may switch you to a different medicine to treat your high blood pressure.

What Is Edarbyclor?

Edarbyclor is a prescription medicine that contains azilsartan medoxomil, an angiotensin receptor blocker (ARB) and chlorthalidone, a water pill (diuretic).

Edarbyclor is used to treat high blood pressure (hypertension):

- when one medicine to lower your high blood pressure is not enough
- as the first medicine to lower your high blood pressure if your doctor decides you are likely to need more than one medicine.

It is not known if Edarbyclor is safe and effective in children under 18 years of age.

Who should not take Edarbyclor?

Do not take Edarbyclor if you:

- make less urine because of kidney problems

What should I tell my doctor before taking Edarbyclor?

Before you take Edarbyclor, tell your doctor if you:

- have been told that you have abnormal body salt (electrolytes) levels in your blood
- have liver or kidney problems
- have heart problems or stroke
- are vomiting or have diarrhea
- have gout
- are pregnant or plan to become pregnant. See **“What is the most important information I should know about Edarbyclor?”**
- are breastfeeding or plan to breastfeed. It is not known if Edarbyclor passes into your breast milk. You and your doctor should decide if you will take Edarbyclor or breastfeed. You should not do both. Talk with your doctor about the best way to feed your baby if you take Edarbyclor.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Especially tell your doctor if you take:

- other medicines used to treat your high blood pressure or heart problem
- water pills (diuretics)

- lithium carbonate (Lithobid), lithium citrate
- digoxin (Lanoxin)

Ask your doctor if you are not sure if you are taking a medicine listed above.

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

How should I take Edarbyclor?

- Take Edarbyclor exactly as your doctor tells you to.
- Your doctor will tell you how much Edarbyclor to take and when to take it.
- Your doctor may prescribe other medicines for you to take along with Edarbyclor to treat your high blood pressure.
- Edarbyclor can be taken with or without food.
- If you miss a dose, take it later in the same day. Do not take more than 1 dose of Edarbyclor in a day.
- If you take too much Edarbyclor and have symptoms of low blood pressure (hypotension) and dizziness, call your doctor for advice. See “What are the possible side effects of Edarbyclor?”

What are the possible side effects of Edarbyclor?

Edarbyclor may cause serious side effects, including:

- **See “What is the most important information I should know about Edarbyclor?”**
- **Low blood pressure (hypotension) and dizziness** is most likely to happen if you also:
 - take water pills (diuretics)
 - are on a low-salt diet
 - take other medicines that affect your blood pressure
 - sweat a lot
 - get sick with vomiting or diarrhea
 - do not drink enough fluids

If you feel faint or dizzy, lie down and call your doctor right away. If you pass out (faint) have someone call your doctor or get medical help. Stop taking Edarbyclor.

- **Kidney problems.** Kidney problems may become worse in people that already have kidney disease. Some people have changes in blood tests for kidney function and may need a lower dose of Edarbyclor or may need to stop treatment with Edarbyclor. During treatment with Edarbyclor, certain people who have severe heart failure, narrowing of the artery to the kidney, or who lose too much body fluid such as with nausea, vomiting, bleeding, or trauma, may develop sudden kidney failure and in rare instances, death.
- **Fluid and body salt (electrolyte) problems.** Tell your doctor if you get any of the following symptoms:

- dry mouth
- thirst
- lack of energy (lethargic)
- weakness
- drowsiness
- confusion
- seizures
- muscle pain or cramps
- restlessness
- muscle tiredness (fatigue)
- passing very little urine or passing large amounts of urine
- fast or abnormal heartbeat
- nausea and vomiting
- constipation

- **Increased uric acid levels in the blood.** People who have increased levels of uric acid in the blood may develop gout. If you already have gout, tell your doctor about worsening of your gout symptoms.

The most common side effects of Edarbyclor are:

- dizziness, and
- tiredness

These are not all the possible side effects with Edarbyclor. Tell your doctor if you have any side effect that bothers you or that does not 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 Edarbyclor?

- Store Edarbyclor at room temperature between 68°F to 77°F (20°C to 25°C).
- Store Edarbyclor in the original container that you received from your pharmacist or doctor. Do not put Edarbyclor into a different container.
- Keep the container closed tightly, and keep Edarbyclor out of the light.

Keep Edarbyclor and all medicines out of the reach of children.

General information about Edarbyclor

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use Edarbyclor for a condition for which it was not prescribed. Do not give Edarbyclor to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about Edarbyclor. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Edarbyclor that is written for health professionals.

For more information, go to www.edarbyclor.com or call 1-866-516-4950.

What is high blood pressure (hypertension)?

Blood pressure is the force in your blood vessels when your heart beats and when your heart rests. You have high blood pressure when the force is too great.

High blood pressure makes the heart work harder to pump blood through the body and causes damage to the blood vessels. Edarbyclor tablets can help your blood vessels relax so your blood pressure is lower. Medicines that lower your blood pressure may lower your chance of having a stroke or heart attack.

What are the ingredients in Edarbyclor?

Active ingredients: azilsartan medoxomil and chlorthalidone

Inactive ingredients: mannitol, microcrystalline cellulose, fumaric acid, sodium hydroxide, hydroxypropyl cellulose, crospovidone, magnesium stearate, hypromellose 2910, talc, titanium dioxide, ferric oxide red, polyethylene glycol 8000, and printing ink gray F1.

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

Manufactured by:



Osaka, Japan

Manufactured for:



Atlanta, GA 30328

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