

PATIENT COUNSELING INFORMATION

Patient Information
Edarbi (eh-DAR-bee)
(azilsartan medoxomil)
Tablets

Read this Patient Information leaflet before you start taking Edarbi 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 Edarbi?

- Edarbi 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 Edarbi, tell your doctor right away. Your doctor may switch you to a different medicine to treat your high blood pressure.

What is Edarbi?

Edarbi is a prescription medicine called an angiotensin II receptor blocker (ARB) used to treat high blood pressure (hypertension) in adults.

Your doctor may prescribe other medicines for you to take along with Edarbi to treat your high blood pressure.

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

What should I tell my doctor before taking Edarbi?

Before you take Edarbi, tell your doctor if you:

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

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 (diuretic)

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 Edarbi?

- Your doctor will tell you how much Edarbi to take and when to take it. Follow his/her instructions.
- Edarbi can be taken with or without food.
- If you take too much Edarbi, call your doctor or go to the nearest hospital emergency room right away.

What are the possible side effects of Edarbi?

Edarbi may cause side effects, including:

- **Harm or death to your unborn fetus if taken in the second or third trimester.** See “**What is the most important information I should know about Edarbi?**”
- **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
 - 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.

These are not all the possible side effects with Edarbi. 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 do I store Edarbi?

- Store Edarbi at 59°F to 86°F (15°C to 30°C).
- Store Edarbi in the original container that you received from your pharmacist or doctor. Do not put Edarbi into a different container.
- Keep Edarbi in a tightly closed container, and keep Edarbi out of the light.

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

General information about Edarbi.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not give Edarbi 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 Edarbi. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Edarbi that is written for health professionals.

For more information, go to www.edarbi.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. Edarbi 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 Edarbi?

Active ingredient: azilsartan medoxomil

Inactive ingredients: mannitol, fumaric acid, sodium hydroxide, hydroxypropyl cellulose, croscarmellose sodium, microcrystalline cellulose, and magnesium stearate.

Manufactured by:



Osaka, Japan

Manufactured for:



Atlanta, GA 30328

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