Package leaflet: Information for the user

Edarbi 20 mg tablets
Edarbi 40 mg tablets
Edarbi 80 mg tablets
azilsartan medoxomil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Edarbi is and what it is used for

Edarbi contains an active substance called azilsartan medoxomil and belongs to a class of medicines called angiotensin II receptor antagonists (AIIRAs). Angiotensin II is a substance which occurs naturally in the body and which causes the blood vessels to tighten, therefore increasing your blood pressure. Edarbi blocks this effect so that the blood vessels relax, which helps lower your blood pressure.

This medicine is used for treating high blood pressure (essential hypertension) in adult patients (over 18 years of age).

A reduction in your blood pressure will be measureable within 2 weeks of initiation of treatment and the full effect of your dose will be observed by 4 weeks.

2. What you need to know before you take Edarbi

Do NOT take Edarbi if you
- are **allergic** to azilsartan medoxomil or any of the other ingredients of this medicine (listed in section 6).
- are **more than 3 months pregnant.** (It is also better to avoid this medicine in early pregnancy - see pregnancy section).
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing **aliskiren**.

Warnings and precautions
Talk to your doctor before taking Edarbi, especially if you
- have kidney problems.
- are on dialysis or had a recent kidney transplant.
- have severe liver disease.
- have heart problems (including heart failure, recent heart attack).

- have ever had a stroke.
- have low blood pressure or feel dizzy or lightheaded.
- are vomiting, have recently had severe vomiting, or have diarrhoea.
- have raised levels of potassium in your blood (as shown in blood tests).
- have a disease of the adrenal gland called primary hyperaldosteronism.
- have been told that you have a narrowing of the valves in your heart (called "aortic or mitral valve stenosis") or that the thickness of your heart muscle is abnormally increased (called "obstructive hypertrophic cardiomyopathy").
- are taking any of the following medicines used to treat high blood pressure:
    - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
    - aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "Do not take Edarbi".
You must tell your doctor if you think you are (or might become) pregnant. Edarbi is not recommended in early pregnancy, and must NOT be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see section "Pregnancy section and breast-feeding"). Edarbi may be less effective in lowering the blood pressure in black patients.

Children and adolescents
There is limited data on the use of Edarbi in children or adolescents under 18 years of age. Therefore, this medicine should not be given to children or adolescents.

Other medicines and Edarbi
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Edarbi can affect the way some other medicines work and some medicines can have an effect on Edarbi.

In particular, tell your doctor if you are taking any of the following medicines:
- Lithium (a medicine for mental health problems)
- Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, diclofenac or celecoxib (medicines to relieve pain and inflammation)
- Acetylsalicyclic acid if taking more than 3 g per day (medicine to relieve pain and inflammation)
- Medicines that increase the amount of potassium in your blood; these include potassium supplements, potassium-sparing medicines (certain 'water tablets') or salt substitutes containing potassium
- Heparin (a medicine for thinning the blood)
- Diuretics (water tablets)
- Aliskiren or other medicines to lower your blood pressure (angiotensin converting enzyme inhibitor or angiotensin II receptor blocker, such as enalapril, lisinopril, ramipril or valsartan, telmisartan, irbesartan).

Your doctor may need to change your dose and/or to take other precautions if you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Edarbi" and "Warnings and precautions").

Pregnancy and breast-feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking this medicine before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Edarbi.

Edarbi is not recommended in early pregnancy, and must NOT be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding
Tell your doctor if you are breast-feeding. Edarbi is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines
Edarbi is unlikely to have an effect on driving or using machines. However some people may feel tired or dizzy when taking this medicine and if this happens to you, do not drive or use any tools or machines.

Edarbi contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Edarbi

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. It is important to keep taking Edarbi every day at the same time.
Edarbi is for oral use. Take the tablet with plenty of water.
You can take this medicine with or without food.

- The usual starting dose is 40 mg once a day. Your doctor may increase this dose to a maximum of 80 mg once a day depending on blood pressure response.
- For patients such as the very elderly (75 years and above) your doctor may recommend a lower starting dose of 20 mg once a day.
- If you suffer from mild or moderate liver disease your doctor may recommend a lower starting dose of 20 mg once a day.
- For patients who recently have lost body fluids e.g. through vomiting or diarrhoea, or by taking water tablets, your doctor may recommend a lower starting dose of 20 mg once a day.
- If you suffer from other coexisting illnesses such as severe kidney disease or heart failure your doctor will decide on the most appropriate starting dose.

If you take more Edarbi than you should
If you take too many tablets, or if someone else takes your medicine, contact your doctor immediately. You may feel faint or dizzy if you have taken more than you should.

If you forget to take Edarbi
Do not take a double dose to make up for a forgotten dose. Just take the next dose at the usual time.

If you stop taking Edarbi
If you stop taking Edarbi, your blood pressure may increase again. Therefore do not stop taking Edarbi without first talking to your doctor about alternative treatment options.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Edarbi and seek medical help immediately if you have any of the following allergic reactions, which occur rarely (may affect up to 1 in 1,000 people):

- Difficulties in breathing, or swallowing, or swelling of the face, lips, tongue and/or throat (angioedema)
- Itching of the skin with raised lumps.

Other possible side effects include:
Common side effects (may affect up to 1 in 10 people):
- Dizziness
- Diarrhoea
- Increased blood creatine phosphokinase (an indicator of muscle damage).

Uncommon side effects (may affect up to 1 in 100 people):
- Low blood pressure, which may make you feel faint or dizzy
- Feeling tired
- Swelling of the hands, ankles or feet (peripheral oedema)
- Skin rash and itching
- Nausea
- Muscle spasms
- Increased serum creatinine in the blood (an indicator of kidney function)
- Increased uric acid in the blood.

Rare side effects (may affect up to 1 in 1,000 people):
- Changes in blood test results including decreased levels of a protein in the red blood cells (haemoglobin).

When Edarbi is taken with chlortalidone (a water tablet), higher levels of certain chemicals in the blood (such as creatinine), which are indicators of kidney function, have been seen commonly (in less than 1 in 10 users), and low blood pressure is also common.

Swelling of the hands, ankles or feet is more common (in less than 1 in 10 users) when Edarbi is taken with amlodipine (a calcium channel blocker for treating hypertension) than when Edarbi is taken alone (less than 1 in 100 users). The frequency of this effect is highest when amlodipine is taken alone.

Reporting of side effects
If you get any side effects talk to your doctor. This includes any side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Edarbi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of the month.

Store Edarbi in the original package in order to protect it from light and moisture.
This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Edarbi contains

- The **active substance** is azilsartan medoxomil (as potassium).

Edarbi 20 mg: Each tablet contains 20 mg azilsartan medoxomil (as potassium)
Edarbi 40 mg: Each tablet contains 40 mg azilsartan medoxomil (as potassium)
Edarbi 80 mg: Each tablet contains 80 mg azilsartan medoxomil (as potassium)

- The **other ingredients** are mannitol, fumaric acid, sodium hydroxide, hydroxypropylcellulose, croscarmellose sodium, microcrystalline cellulose, and magnesium stearate.

What Edarbi looks like and contents of the pack

The tablets are white round debossed with "ASL" on one side and either "20", "40" or "80" on the other.

Edarbi is provided in blisters with either 14 tablets or 15 tablets in cartons containing 14, 28, 56 or 98 tablets and blisters integrated with desiccant with either 14 tablets or 15 tablets in cartons containing 14, 28, 30, 56, 90 or 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Takeda Pharma A/S, Delta Park 45, 2665 Vallensbaek Strand, Denmark

Manufacturer:
Takeda Ireland Limited, Bray Business Park, Kilruddery, Co. Wicklow, Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu