EMA/607910/2013
EMEA/H/C/002293

EPAR summary for the public

Edarbi

azilsartan medoxomil

This is a summary of the European public assessment report (EPAR) for Edarbi. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Edarbi.

What is Edarbi?

Edarbi is a medicine that contains the active substance azilsartan medoxomil. It is available as tablets (20, 40 and 80 mg).

What is Edarbi used for?

Edarbi is used in adults who have essential hypertension (high blood pressure). 'Essential' means that the hypertension has no obvious cause.

The medicine can only be obtained with a prescription.

How is Edarbi used?

Edarbi is taken by mouth and the usual recommended dose is 40 mg once a day. If the blood pressure is not sufficiently controlled, the dose can be increased to 80 mg, or another medicine for hypertension, such as chlortalidone or hydrochlorothiazide, can be added.

How does Edarbi work?

The active substance in Edarbi, azilsartan medoxomil, is an 'angiotensin II receptor antagonist', which means that it blocks the action of a hormone in the body called angiotensin II. Angiotensin II is a powerful vasoconstrictor (a substance that narrows blood vessels). By blocking the receptors to which angiotensin II normally attaches, azilsartan medoxomil stops the hormone from having an effect,

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

therefore allowing the blood vessels to widen. This allows the blood pressure to fall towards normal, thus reducing the risks associated with high blood pressure, such as having a stroke.

How has Edarbi been studied?

Eight main studies involving over 6,000 patients with essential hypertension were carried out with Edarbi.

Five studies investigated the effects of Edarbi taken alone, comparing it with placebo (a dummy treatment) or with other antihypertensive medicines (ramipril, valsartan and olmesartan medoxomil). The patients in these studies had mild to moderate hypertension.

Three studies investigated the effects of Edarbi in combination with other antihypertensive medicines (chlortalidone, amlodipine, and hydrochlorothiazide). The patients in the combination studies had moderate to severe hypertension.

The studies lasted between six and 56 weeks and the main measure of effectiveness was the change in the systolic blood pressure (blood pressure when the heart is contracting).

What benefit has Edarbi shown during the studies?

Edarbi on its own was more effective than placebo. In the two studies with Edarbi taken alone compared with placebo, patients had an average fall in systolic blood pressure of about 13.5 mmHg on Edarbi 40 mg and a fall of about 14.5 mmHg on Edarbi 80 mg after 6 weeks. This compares with a fall of 0.3 to 1.4 mmHg in the patients taking placebo.

When Edarbi alone was compared with other medicines, 80 mg of Edarbi was more effective in lowering blood pressure than the highest approved dose of valsartan (320 mg) and olmesartan medoxomil (40 mg). Edarbi 40 and 80 mg was also more effective than ramipril (10 mg).

The studies also showed that Edarbi, when taken in combination with other medicines, can produce additional decreases in blood pressure compared with when these medicines are taken without Edarbi.

What is the risk associated with Edarbi?

Side effects with Edarbi are generally mild or moderate, with the most common side effect being dizziness. For the full list of all side effects reported with Edarbi, see the package leaflet.

Edarbi must not be used in women who are more than three months pregnant. Its use during the first three months of pregnancy is also not recommended. Edarbi must also not be used in combination with aliskiren-containing medicines (also used to treat essential hypertension) in patients with diabetes or in patients with moderate or severe kidney impairment. For the full list of restrictions, see the package leaflet.

Why has Edarbi been approved?

The CHMP concluded that Edarbi belongs to an established class of medicines in the treatment of hypertension and its risks are similar to others within this class. The Committee decided that the benefits of Edarbi are greater than its risks in patients with essential hypertension and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Edarbi?

A risk management plan has been developed to ensure that Edarbi is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Edarbi, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Edarbi

The European Commission granted a marketing authorisation valid throughout the European Union for Edarbi on 07 December 2011.

The full EPAR for Edarbi can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Edarbi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2013.