



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 September 2011  
EMA/CHMP/736839/2011  
Committee for Medicinal Products for Human Use (CHMP)

## **Summary of opinion<sup>1</sup> (initial authorisation)**

---

### Edarbi

#### azilsartan medoxomil

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Edarbi, 20 mg, 40 mg, 80 mg, tablet intended for the treatment of essential hypertension in adults. The applicant for this medicinal product is Takeda Global Research and Development Centre (Europe) Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Edarbi is azilsartan medoxomil, an angiotensin II receptor antagonist (ATC code: C09CA09). By potently, selectively and competitively blocking the angiotensin II type 1 receptors, Edarbi inhibits the Renin Angiotensin Aldosterone system resulting in a reduction in blood pressure.

The benefit of Edarbi is its ability to effectively lower the blood pressure. The most common side effects are dizziness, diarrhoea and blood creatinine phosphokinase increased. Uncertainties are present regarding the dosing and safety in complicated patients, such as the very elderly (> 75 years), patients with an activated Renin Angiotensin Aldosterone system (e.g. patients with heart failure), and patients with renal and liver insufficiency.

A pharmacovigilance plan for Edarbi will be implemented as part of the marketing authorisation.

The approved indication is: "Treatment of essential hypertension in adults".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European Public Assessment Report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Edarbi and therefore recommends the granting of the marketing authorisation.

---

<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

