Abbreviated Prescribing Information – Edarbi® (azilsartan medoxomil) (Refer to the Summary of Product Characteristics before prescribing) **Presentation:** Tablets containing 20mg, 40mg or 80mg of azilsartan medoxomil **Indication:** Essential hypertension in adults **Dosage:** Starting dose is 40mg once daily with or without food. The dose may be increased to 80mg in patients not adequately controlled at lower dose. Maximal antihypertensive effect is attained by 4 weeks. No initial dose adjustment in the elderly (65 years and older) or those with mild or moderate renal impairment. 20mg as a starting dose should be considered in the very elderly (≥75 years), in patients with mild to moderate hepatic impairment and in patients with possible depletion of intravascular volume or salt depletion. Additional blood pressure reduction can be achieved when Edarbi® is co-administered with other antihypertensive medicinal products, including diuretics and calcium channel blockers **Contraindications:** Hypersensitivity to any component of Edarbi®. Second and third trimester of pregnancy. **Warnings and Precautions:** In patients with an activated renin-angiotensin-aldosterone system (e.g. congestive heart failure, severe renal impairment or renal artery stenosis) the use of angiotensin II receptor antagonists, has been associated with acute hypotension, azotaemia, oliguria or, rarely, acute renal failure. The possibility of similar effects cannot be excluded with Edarbi®. Edarbi® should be used with caution in hypertensive patients with severe renal impairment, congestive heart failure or renal artery stenosis or those who have recently undergone kidney transplantation as there is no experience of use of Edarbi® in these patients. In patients with ischaemic cardiomyopathy or ischaemic cerebrovascular disease excessive blood pressure decreases could result in myocardial infarction or stroke. Edarbi® is not recommended in patients with severe hepatic impairment or primary hyperaldosteronism. In patients with marked volume- and/or salt-depletion symptomatic hypotension could occur after initiation of treatment with Edarbi®. Hypovolemia should be corrected prior to treatment which should start under close medical supervision. Concomitant use of Edarbi® with potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium and other medicinal products that may increase potassium levels (e.g heparin) may lead to hyperkalaemia in hypertensive patients. The risk of hyperkalaemia is increased in the elderly, in patients with renal insufficiency, in diabetic patients and in patients with other co-morbidities. Monitoring of potassium should be undertaken as appropriate. Special caution in patients suffering from aortic or mitral valve stenosis, or hypertrophic obstructive cardiomyopathy (HOCM). Edarbi® should not be initiated during pregnancy. When pregnancy is confirmed treatment with Edarbi® should be stopped immediately. Edarbi® is not recommended during breastfeeding. **Drug Interactions:** No clinically significant interactions with amlodipine, antacids, chlortalidone, digoxin, fluconazole, glyburide, ketoconazole, metformin, and warfarin. Use with lithium is not recommended. If the combination proves necessary, careful monitoring of serum lithium levels is recommended. Attenuation of the antihypertensive effect may occur with NSAIDs and use with NSAIDs may lead to worsening of renal function and increase in serum potassium. Therefore adequate hydration and monitoring of renal function at the beginning of treatment is recommended. **Side Effects:** *Prescribers should consult the Summary of Product Characteristics in relation to other side-effects.* In clinical studies of up to 56 weeks, adverse reactions were mostly mild or moderate, with an overall incidence similar to placebo. The incidence of adverse reactions with Edarbi® was not affected by gender, age, or race. These are ranked by frequency, using the following convention: very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (< 1/10,000), including isolated reports. The most common adverse reaction was dizziness. Other adverse reactions seen commonly in clinical trials include diarrhoea and increased blood creatine phosphokinase. Uncommon adverse reactions include hypotension, fatigue, peripheral oedema, increased blood creatinine and hyperuricemia. Angioedema, including circumoral oedema and periorbital oedema, was rarely seen in patients during open label treatment. Co-administration with chlortalidone increased the frequencies of increased blood creatinine and hypotension from uncommon to common. Co-administration with amlodipine increased the frequency of peripheral oedema from uncommon to common, but was lower than amlodipine alone. **Legal Category:** POM **Packs and Basic NHS Price:** Edarbi® 20mg, £16.80 for 28 tablets (EU/1/11/734/002), Edarbi® 40mg, £16.80 for 28 tablets (EU/1/11/734/006) and Edarbi® 80mg, £19.95 for 28 tablets (EU/1/11/734/009). **PI approval code**: AZL120107a **PI Date of Preparation:** February 2012 **Marketing Authorisation Holder:** Takeda Global Research and Development Centre (Europe) Ltd., 61 Aldwych, London, WC2B 4AE, UK. **Further information can be obtained from:** Takeda UK Ltd. Takeda House, Mercury Park, Wooburn Green, High Wycombe, Bucks HP10 0HH. 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Please refer to the Summary of Product Characteristics for details on the full side-effect profile and drug interactions of Edarbi®. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Takeda UK Ltd. on 01628 537900.

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