

ZILSAR

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for ZILSAR [Azilsartan Medoxomil Tablets I.P. 40 mg and 80 mg]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Azilsartan medoxomil is an orally active prodrug that is rapidly converted to the active moiety, azilsartan, which selectively antagonises the effects of angiotensin II by blocking its binding to the AT1 receptor in multiple tissues. Angiotensin II is the principal pressor agent of the RAAS, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. Blockade of the AT1 receptor inhibits the negative regulatory feedback of angiotensin II on renin secretion, but the resulting increases in plasma renin activity and angiotensin II circulating levels do not overcome the antihypertensive effect of azilsartan.

INDICATIONS: Azilsartan is indicated for the treatment of hypertension in adult patient, either alone or in combination with other antihypertensive agents.

DOSAGE AND ADMINISTRATION: Azilsartan Medoxomil is for oral use and may be taken with or without food.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Second and third trimester of pregnancy. The concomitant use of Azilsartan Medoxomil with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment ($GFR < 60 \text{ mL/min/1.73m}^2$).

WARNINGS & PRECAUTIONS: Caution should be exercised in hypertensive patients with severe renal impairment, congestive heart failure or renal artery stenosis, as there is no experience of use of Azilsartan Medoxomil in these patients. Excessive blood pressure decreases in patients with ischaemic cardiomyopathy or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke. Dual blockade of RAAS through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is therefore not recommended. ACE-inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy. Hypovolemia should be corrected prior to administration of Azilsartan Medoxomil. In the elderly, in patients with renal insufficiency, in diabetic patients and/or in patients with other co-morbidities, the risk of hyperkalaemia, which may be fatal, is increased. Special caution is indicated in patients suffering from aortic or mitral valve stenosis, or hypertrophic obstructive cardiomyopathy (HOCM). When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately.

DRUG INTERACTIONS: Due to the lack of experience with concomitant use of azilsartan medoxomil and lithium, this combination is not recommended. Concomitant use of angiotensin II receptor antagonists and NSAIDs may lead to an increased risk of worsening of renal function and an increase in serum potassium. Therefore, adequate hydration and monitoring of renal function at the beginning of the treatment are recommended. Concomitant use of potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, or other medicinal products (e.g. heparin) may increase potassium levels. Monitoring of serum potassium should be undertaken as appropriate.

ADVERSE REACTIONS: Dizziness, Hypotension, Diarrhoea, Nausea, Rash, pruritus, Angioedema, Muscle spasms, Fatigue, Peripheral oedema, Blood creatine phosphokinase increased, Blood creatinine increased, Hyperuricemia.

MARKETED BY:



Torrent Pharmaceuticals Limited.

IN/ ZILSAR 40, 80 MG/MAY-2025/02/ABPI

(Additional information is available on request)