European Medicines Agency

EMEA/H/C/852

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

TEKTURNA

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Tekturna?
Tekturna is a medicine that contains the active substance aliskiren. It is available as tablets (pink and round: 150 mg; red and oval: 300 mg).

What is Tekturna used for?
Tekturna is used to treat 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 Tekturna used?
The recommended dose of Tekturna is 150 mg once a day, either taken alone or in combination with other medicines for hypertension. It should be taken with a light meal preferably at the same time each day, but grapefruit juice should not be taken together with Tekturna. The dose of Tekturna may be increased to 300 mg once a day in patients whose blood pressure is not adequately controlled. Tekturna is not recommended for use in patients below 18 years of age, because of a lack of information on safety and effectiveness in this age group.

How does Tekturna work?
The active substance in Tekturna, aliskiren, is a renin inhibitor. It blocks the activity of a human enzyme called renin, which is involved in the production of a substance called angiotensin I in the body. Angiotensin I is converted into the hormone angiotensin II, which is a powerful vasoconstrictor (a substance that narrows blood vessels). By blocking the production of angiotensin I, levels of both angiotensin I and angiotensin II fall. This causes vasodilation (widening of the blood vessels), so that the blood pressure drops. This may reduce the risks associated with high blood pressure, such as having a stroke.

How has Tekturna been studied?
The effects of Tekturna were first tested in experimental models before being studied in humans. Tekturna was studied in 14 main studies involving over 10,000 patients with essential hypertension. Thirteen of the studies included patients with mild to moderate hypertension, and one included patients with severe hypertension. In five of the studies, the effects of Tekturna taken alone were

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

compared with those of placebo (a dummy treatment). Tekturna, taken alone or in combination with other medicines, was also compared with other medicines for hypertension. Combination studies looked at Tekturna used with an angiotensin converting enzyme inhibitor (ramipril), an angiotensin receptor blocker (valsartan), a beta-blocker (atenolol), a calcium-channel blocker (amlodipine) and a diuretic (hydrochlorothiazide). The studies lasted between six and 52 weeks and the main measure of effectiveness was the change in blood pressure during either the resting phase of the heartbeat (diastolic) or when the chambers of the heart were contracting (systolic). The blood pressure was measured in 'millimetres of mercury' (mmHg).

What benefit has Tekturna shown during the studies?
Tekturna on its own was more effective than placebo and as effective as comparator treatments in reducing blood pressure. When the results of the five studies comparing Tekturna taken alone with placebo were looked at together, patients aged under 65 years had an average fall in diastolic blood pressure of 9.0 mmHg after eight weeks of taking 150 mg Tekturna, from an average of 99.4 mmHg at the start of the study. This was compared with a fall of 5.8 mmHg from 99.3 mmHg in the patients taking placebo.
Larger falls were seen in patients aged 65 years or over and those taking higher doses of Tekturna. Tekturna also reduced blood pressure in patients with diabetes and patients who were overweight. The medicine's effects were maintained for up to a year in two of the studies.
The studies also showed that Tekturna, when taken in combination with other medicines (especially hydrochlorothiazide), can produce additional decreases in blood pressure compared with the decreases produced by these medicines when they are taken without Tekturna.

What is the risk associated with Tekturna?
The most common side effect with Tekturna (seen in between 1 and 10 patients in 100) is diarrhoea. For the full list of all side effects reported with Tekturna, see the Package Leaflet.
Tekturna should not be used by people who may be hypersensitive (allergic) to aliskiren or any of the other ingredients. It must not be in patients who have had angioedema (swelling under the skin) with aliskiren or in women who are more than three months pregnant. Its use during the first three months of pregnancy and in women planning to become pregnant is not recommended. Tekturna must also not be taken with ciclosporin (a medicine that reduces the activity of the immune system), quinidine (used to correct irregular heartbeat) or verapamil (used to treat heart problems).

Why has Tekturna been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that the benefits of Tekturna are greater than its risks for the treatment of essential hypertension. The Committee recommended that Tekturna be given marketing authorisation.

Other information about Tekturna:
The European Commission granted a marketing authorisation valid throughout the European Union for Tekturna to Novartis Europharm Limited on 22 August 2007.

The full EPAR for Tekturna can be found here.

This summary was last updated in 04-2009.