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EPAR summary for the public

Telmisartan Actavis

telmisartan

This is a summary of the European public assessment report (EPAR) for Telmisartan Actavis. 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 Telmisartan Actavis.

What is Telmisartan Actavis?

Telmisartan Actavis is a medicine that contains the active substance telmisartan. It is available as tablets (20 mg; 40 and 80 mg).

Telmisartan Actavis is a 'generic medicine'. This means that Telmisartan Actavis is similar to a 'reference medicine' already authorised in the European Union (EU) called Micardis. For more information on generic medicines, see the question-and-answer document here.

What is Telmisartan Actavis used for?

Telmisartan Actavis is used to treat essential hypertension (high blood pressure) in adults. 'Essential' means that the hypertension has no obvious cause.

Telmisartan Actavis is also used to prevent cardiovascular problems (problems with the heart and blood vessels) such as heart attacks or strokes. It is used in patients who have had problems due to blood clots in the past (such as heart disease, a stroke or artery disease) or who have type 2 diabetes that has damaged an organ (such as the eyes, heart or kidneys).

The medicine can only be obtained with a prescription.

How is Telmisartan Actavis used?

For the treatment of essential hypertension, the usual recommended dose of Telmisartan Actavis is 40 mg once a day, but some patients may benefit from using 20 mg once a day. If the target blood

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pressure is not reached, the dose can be increased to 80 mg, or another medicine for hypertension can be added, such as hydrochlorothiazide.

For the prevention of cardiovascular problems, the recommended dose is 80 mg once a day. The doctor should monitor the patient's blood pressure closely when starting Telmisartan Actavis, and may decide to adjust the patient's blood pressure-lowering medication. Patients with severely reduced kidney function should receive a lower starting dose of 20 mg once a day. Patients with mild or moderately reduced liver function should not receive doses higher than 40 mg a day.

How does Telmisartan Actavis work?

The active substance in Telmisartan Actavis, telmisartan, 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, telmisartan stops the hormone having an effect, allowing the blood vessels to widen. This allows the blood pressure to drop, reducing the risks associated with high blood pressure, such as having a heart attack or stroke. It also allows the heart to pump blood more easily, which can help to reduce the risk of future cardiovascular problems.

How has Telmisartan Actavis been studied?

Because Telmisartan Actavis is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Micardis. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Telmisartan Actavis?

Because Telmisartan Actavis is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Telmisartan Actavis been approved?

The CHMP concluded that, in accordance with EU requirements, Telmisartan Actavis has been shown to have comparable quality and to be bioequivalent to Micardis. Therefore, the CHMP's view was that, as for Micardis, the benefit outweighs the identified risk. The Committee recommended that Telmisartan Actavis be given marketing authorisation.

Other information about Telmisartan Actavis:

The European Commission granted a marketing authorisation valid throughout the European Union for Telmisartan Actavis on 30 September 2010.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 06-2015.