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EPAR summary for the public

Telmisartan Teva

telmisartan

Medicinal product no longer authorised

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

What is Telmisartan Teva?

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

Telmisartan Teva is a 'generic medicine'. This means that Telmisartan Teva 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 Teva used for?

Telmisartan Teva is used in adults who have essential hypertension (high blood pressure). 'Essential' means that the hypertension has no obvious cause.

Telmisartan Teva 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 Teva used?

For the treatment of essential hypertension, the recommended dose of Telmisartan Teva is 40 mg once a day, but some patients may benefit from using a 20 mg dose. If the target blood pressure is not

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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 Teva, 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 Teva work?

The active substance in Telmisartan Teva, 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 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 Teva been studied?

Because Telmisartan Teva 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 Teva?

Because Telmisartan Teva 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 Teva been approved?

The CHMP concluded that, in accordance with EU requirements, Telmisartan Teva 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 Teva be given marketing authorisation.

Other information about Telmisartan Teva

The European Commission granted a marketing authorisation valid throughout the EU for Telmisartan Teva on 26 January 2010.

The full EPAR for Telmisartan Teva can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Telmisartan Teva, 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.

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