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**EPAR summary for the public**

# Tolura

telmisartan

This document is a summary of the European Public Assessment Report (EPAR) for Tolura. 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 Tolura.

## What is Tolura?

Tolura is a medicine that contains the active substance telmisartan. It is available as white tablets (round: 20 mg; oval: 40 mg; capsule-shaped: 80 mg).

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

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

Tolura is also used to prevent cardiovascular problems (problems with the heart and blood vessels) such as heart attacks. It is used in patients who have had problems due to blood clots in the past (such as heart disease 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 Tolura used?

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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 Tolura, and may decide to adjust the patient's blood pressure-lowering medication.

## How does Tolura work?

The active substance in Tolura, 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. It also allows the heart to pump blood more easily, which can help to reduce the risk of future cardiovascular problems.

## How has Tolura been studied?

Because Tolura is a generic medicine, studies in patients 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 benefit and risk of Tolura?

Because Tolura is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as the reference medicine's.

## Why has Tolura been approved?

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

## Other information about Tolura:

The European Commission granted a marketing authorisation valid throughout the EU for Tolura to Krka, d.d., Novo mesto on 4 June 2010. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Tolura can be found on the Agency's website: EMA website/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Tolura, 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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