EMA/40538/2013
EMEA/H/C/002549

EPAR summary for the public

Tolucombi

telmisartan / hydrochlorothiazide

This is a summary of the European public assessment report (EPAR) for Tolucombi. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Tolucombi.

For practical information about using Tolucombi, patients should read the package leaflet or contact their doctor or pharmacist.

What is Tolucombi and what is it used for?

Tolucombi is a medicine that contains two active substances, telmisartan and hydrochlorothiazide. It is used in adults who have essential hypertension (high blood pressure) that is not adequately controlled by telmisartan alone. 'Essential' means that the hypertension has no obvious cause.

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

How is Tolucombi used?

Tolucombi is available as tablets (40 mg or 80 mg telmisartan and 12.5 mg hydrochlorothiazide; 80 mg telmisartan and 25 mg hydrochlorothiazide) to be taken by mouth once a day with liquid. The dose of Tolucombi to be used depends on the dose of telmisartan that the patient was taking before: patients who were receiving 40 mg telmisartan should take the 40/12.5 mg tablets, and patients who were receiving 80 mg telmisartan should take the 80/12.5 mg tablets. The 80/25 mg tablets are used in patients whose blood pressure is not controlled using the 80/12.5 mg tablets or who have been stabilised using the two active substances taken separately before switching to Tolucombi.

The medicine can only be obtained with a prescription.

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How does Tolucombi work?

Tolucombi contains two active substances, telmisartan and hydrochlorothiazide.

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.

Hydrochlorothiazide is a diuretic, which is another type of treatment for hypertension. It works by increasing urine output, reducing the amount of fluid in the blood and reducing the blood pressure.

The combination of the two active substances has an additive effect, reducing the blood pressure more than either medicine alone. By lowering the blood pressure, the risks associated with high blood pressure, such as having a stroke, are reduced.

How has Tolucombi been studied?

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

What are the benefits and risks of Tolucombi?

Because Tolucombi 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 is Tolucombi approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Tolucombi has been shown to have comparable quality and to be bioequivalent to MicardisPlus. Therefore, the CHMP's view was that, as for MicardisPlus, the benefit outweighs the identified risk. The Committee recommended that Tolucombi be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Tolucombi?

A risk management plan has been developed to ensure that Tolucombi is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tolucombi, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Tolucombi

The European Commission granted a marketing authorisation valid throughout the European Union for Tolucombi on 13 March 2013.

The full EPAR for Tolucombi 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 Tolucombi, 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 03-2013.