

Summary Public Assessment Report

Telmisartan AmaroX (telmisartan)

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Telmisartan Amarox
telmisartan

Tablet, 20 mg, 40 mg, 80 mg

This is a summary of the public assessment report (PAR) for Telmisartan Amarox. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Telmisartan Amarox and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Micardis.

Telmisartan Amarox is used to treat essential hypertension (high blood pressure) in adults. 'Essential' means that the high blood pressure is not caused by any other condition. High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range.

Telmisartan Amarox is also used to reduce cardiovascular events (i.e. heart attack or stroke) in adults who are at risk because they have a reduced or blocked blood supply to the heart or legs, or have had a stroke or have high risk diabetes. Your doctor can tell you if you are at high risk for such events.

How does Telmisartan Amarox work?

Telmisartan Amarox belongs to a class of medicines known as angiotensin II receptor blockers. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. Telmisartan Amarox blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

How is Telmisartan Amarox used?

The pharmaceutical form is tablets for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Telmisartan Amarox have been shown in studies?

Because the product is a generic medicine, studies 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 possible side effects from Telmisartan Amarox?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Telmisartan Amarox approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Micardis, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that the product 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, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Telmisartan Amarox

The full PAR for Telmisartan Amarox can be found on the following website: [MRI - Home](#). For more information about treatment with Telmisartan Amarox, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in YYYY-MM.