

Summary Public Assessment Report

Telmisartan Jubilant (telmisartan)

SE/H/1291/01-03/DC

Summary Public Assessment Report

Telmisartan Jubilant
(telmisartan)

Tablets; 20, 40 and 80 mg

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

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

What is Telmisartan Jubilant and what is it used for?

Telmisartan Jubilant is a ‘generic medicine’. This means that Telmisartan Jubilant is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Micardis. Telmisartan Jubilant is used in the treatment of essential hypertension (high blood pressure) in adults. ‘Essential’ means that the high blood pressure is not caused by any other condition. Telmisartan Jubilant 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 Jubilant work?

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

How is Telmisartan Jubilant used?

The pharmaceutical form of Telmisartan Jubilant 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.

What benefits of Telmisartan Jubilant have been shown in studies?

Because Telmisartan Jubilant 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 possible side effects of Telmisartan Jubilant?

Because Telmisartan Jubilant is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Telmisartan Jubilant approved?

It was concluded that, in accordance with EU requirements, Telmisartan Jubilant has been shown to have comparable quality and to be bioequivalent to the reference medicine Micardis. Therefore, the Medical Products Agency in Sweden 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 Jubilant?

A risk management plan has been developed to ensure that Telmisartan Jubilant 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 Telmisartan Jubilant, 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 Jubilant

The marketing authorisation for Telmisartan Jubilant was granted on 2013-11-21 in Sweden.

The full PAR for Telmisartan Jubilant can be found on the following website: <http://mri.medagencies.org/Human/> . For more information about treatment with Telmisartan Jubilant, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2013-11-21.