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EPAR summary for the public

Talmanco[1]

tadalafil

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

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

What is Talmanco and what is it used for?

Talmanco is a medicine used to treat adults with pulmonary arterial hypertension (PAH) to improve exercise capacity (the ability to carry out physical activity). PAH is abnormally high blood pressure in the arteries of the lungs. Talmanco is used in patients with class-II (slight limitation of physical activity) or class-III (marked limitation of physical activity) PAH.

Talmanco contains the active substance tadalafil.

Talmanco is a 'generic medicine'. This means that Talmanco contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Adcirca. For more information on generic medicines, see the question-and-answer document here.

How is Talmanco used?

Talmanco can only be obtained with a prescription and treatment should be started and monitored by a doctor who has experience in the treatment of PAH.

[1] Previously known as Tadalafil Generics.

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Talmanco is available as 20 mg tablets. The recommended dose is two tablets (40 mg) once a day. Patients with mild or moderate kidney or liver problems should be started on a lower dose. Talmanco is not recommended for patients with severe kidney or liver problems.

How does Talmanco work?

PAH is a debilitating disease where there is severe narrowing of the blood vessels of the lungs. This leads to high blood pressure in the vessels taking blood from the heart to the lungs and reduces the amount of oxygen that can get into the blood in the lungs, making physical activity more difficult. The active substance in Talmanco, tadalafil, belongs to a group of medicines called 'phosphodiesterase type 5 (PDE5) inhibitors', which means that it blocks the PDE5 enzyme. This enzyme is found in the blood vessels of the lungs. When the enzyme is blocked, a substance called 'cyclic guanosine monophosphate' (cGMP) cannot be broken down and remains in the vessels where it causes widening of the blood vessels. In patients with PAH, this lowers the blood pressure in the lungs and improves symptoms.

How has Talmanco been studied?

Studies on the benefits and risks of the active substance in the approved use have already been carried out with the reference medicine, Adcirca, and do not need to be repeated for Talmanco.

As for every medicine, the company provided studies on the quality of Talmanco. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Talmanco?

Because Talmanco 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 Talmanco approved?

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

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Talmanco have been included in the summary of product characteristics and the package leaflet.

Other information about Talmanco

The European Commission granted a marketing authorisation valid throughout the European Union for Tadalafil Generics on 9 January 2017. The name of the medicine was changed to Talmanco on 1 March 2017.

The full EPAR for Talmanco 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 Talmanco, 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 05-2017.