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EPAR summary for the public

Thelin

sitaxentan sodium

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

What is Thelin?

Thelin is a medicine that contains the active substance sitaxentan sodium. It is available as yellow-to-orange, capsule-shaped tablets (100 mg).

What is Thelin used for?

Thelin is used to treat adults (aged 18 years or over) 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. Thelin is used in patients with class III disease. The 'class' reflects the seriousness of the disease: 'class III' involves marked limitation of physical activity. Thelin has been shown to be effective in PAH with no identified cause and PAH caused by connective tissue disease.

Because the number of patients with pulmonary arterial hypertension is low, the disease is considered 'rare', and Thelin was designated an 'orphan medicine' (a medicine used in rare diseases) on 21 October 2004.

The medicine can only be obtained with a prescription.

How is Thelin used?

Thelin should only be started and monitored by a doctor who has experience in the treatment of PAH.

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It is taken as one tablet a day, preferably at the same time of the day. This is the maximum dose. If after 12 weeks the patient's condition is getting worse, then the doctor should review the treatment.

How does Thelin work?

PAH is a debilitating disease where there is severe constriction (narrowing) of the blood vessels of the lungs. It causes high blood pressure in the vessels taking blood from the heart to the lungs. This pressure reduces the amount of oxygen that can get into the blood in the lungs, making physical activity more difficult.

The active substance in Thelin, sitaxentan sodium, blocks the receptors for a hormone called endothelin-1 (ET-1), which causes blood vessels to constrict. By blocking the effect of ET-1, Thelin allows the vessels to dilate (expand), helping to lower the blood pressure and improving symptoms.

How has Thelin been studied?

Three doses of Thelin (50, 100 and 300 mg) have been compared with placebo (a dummy treatment) in three main studies involving a total of 523 patients with PAH, most of whom had class II or III disease. The study measured the improvement in exercise capacity by looking at the change in how far the patients could walk in six minutes after 12 to 18 weeks of treatment.

What benefit has Thelin shown during the studies?

Thelin was more effective than placebo at improving exercise capacity. Before treatment, the patients could walk around 366 metres in six minutes. After 12 to 18 weeks, this distance had increased by 33 metres more in the patients taking 100 mg Thelin than in the patients taking placebo. In the patients with class III disease, this was around 46 metres.

What is the risk associated with Thelin?

The most common side effect with Thelin (seen in more than 1 patient in 10) is headache. For the full list of all side effects reported with Thelin, see the package leaflet.

Thelin should not be used in people who may be hypersensitive (allergic) to sitaxentan sodium or any of the other ingredients. It must not be used in patients who have mild to severe problems with their liver or raised levels of some liver enzymes. The patient's liver should be monitored before and during the treatment. Thelin must not be taken with ciclosporin A (a medicine used to treat psoriasis and rheumatoid arthritis, and to prevent rejection of liver and kidney transplants). Thelin must not be used in women who are breastfeeding.

Caution is needed when Thelin is taken at the same time as some other medicines. See the package leaflet for full details.

Why has Thelin been approved?

The CHMP concluded that Thelin had shown an effectiveness that was as expected for this class of medicines. However, the effectiveness was only considered sufficient in patients with class III disease. Therefore, the Committee decided that Thelin's benefits are greater than its risks for patients with class III disease and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe use of Thelin?

The company that makes Thelin will provide doctors and patients with educational material about the medicine. The company will also set up a system to monitor Thelin's side effects, suspected interactions with other medicines and the outcome of any pregnancies that may happen in women using the medicine.

Other information about Thelin:

The European Commission granted a marketing authorisation valid throughout the European Union for Thelin on 10 August 2006. The marketing authorisation holder is Pfizer Limited. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Thelin can be found here. For more information about treatment with Thelin, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Thelin is available here.

This summary was last updated in 08-2010.