EMA/251911/2025
EMEA/H/C/006524

Macitentan Accord (*macitentan*)

An overview of Macitentan Accord and why it is authorised in the EU

What is Macitentan Accord and what is it used for?

Macitentan Accord is a medicine used for the long-term treatment of pulmonary arterial hypertension (PAH), a condition in which there is abnormally high blood pressure in the arteries of the lungs, causing symptoms such as breathlessness and fatigue.

Macitentan Accord is used for adults, adolescents and children weighing at least 40 kg in whom PAH comes with moderate or marked limitations in physical activity (corresponding to WHO functional class II or III, respectively). Macitentan Accord is used as monotherapy.

Macitentan Accord contains the active substance macitentan and is a 'generic medicine'. This means that Macitentan Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Macitentan Accord is Opsumit. For more information on generic medicines, see the question-and-answer document here.

How is Macitentan Accord used?

Macitentan Accord can only be obtained with a prescription and treatment should be started and monitored by a doctor experienced in treating PAH. The medicine is available as tablets to be taken once a day. For more information about using Macitentan Accord, see the package leaflet or contact your doctor or pharmacist.

How does Macitentan Accord work?

In PAH there is severe narrowing of the small blood vessels (arterioles) in the lungs. Because more pressure is needed to force blood through these narrowed vessels, this leads to high blood pressure in the arteries to the lungs.

The active substance in Macitentan Accord, macitentan, works by blocking endothelin receptors. These are part of a natural mechanism in the body that can cause the small blood vessels to narrow. In patients with PAH, this mechanism is overactive and, by blocking these receptors, macitentan helps widen the arterioles in the lungs and thereby bring down the blood pressure.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How has Macitentan Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Opsumit, and do not need to be repeated for Macitentan Accord.

As for every medicine, the company provided studies on the quality of Macitentan Accord. The company also carried out a study 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 Macitentan Accord?

Because Macitentan Accord 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 Macitentan Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Macitentan Accord has been shown to have comparable quality and to be bioequivalent to Opsumit. Therefore, the Agency's view was that, as for Opsumit, the benefits of Macitentan Accord outweigh the identified risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Macitentan Accord have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Opsumit, such as a patient card with key safety information, also apply to Macitentan Accord where appropriate.

As for all medicines, data on the use of Macitentan Accord are continuously monitored. Suspected side effects reported with Macitentan Accord are carefully evaluated and any necessary action taken to protect patients.

Other information about Macitentan Accord

Macitentan Accord received a marketing authorisation valid throughout the EU on 24 September 2025.

Further information on Macitentan Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/macitentan-accord.

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 12-2025.