EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Opsumit

macitentan

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AUTHORISED
This medicine is authorised for use in the European Union.

Overview

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

Opsumit is used for adults whose PAH is classified as WHO functional class II to class III. The class reflects the seriousness of the disease: patients with class II PAH have slight limitation of physical activity and those with class III disease have marked limitation of physical activity. Opsumit can be used alone or in combination with other PAH medicines; for further information, see the package leaflet.

PAH is 'rare', and Opsumit was designated an 'orphan medicine' (a medicine used in rare diseases) for PAH on 27 September 2011.

Opsumit contains the active substance macitentan.

How is Opsumit used?

Opsumit 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 10 mg tablets and taken at a dose of one tablet every day.

For more information about using Opsumit, see the package leaflet or contact your doctor or pharmacist.

How does Opsumit work?

In PAH there is severe narrowing of the arteries of the lungs. Because more pressure is needed to force blood through the narrowed artery, this leads to high blood pressure in the lungs.

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

What benefits of Opsumit have been shown in studies?

In a main study involving 742 patients, Opsumit has been shown to reduce the risk of PAH-related illness, particularly the worsening of PAH symptoms. Patients in the study received either Opsumit or placebo (a dummy treatment) in addition to other PAH treatments for an average of 2 years. Around 37% of patients taking placebo had a worsening of their PAH symptoms compared with 24% of those who took Opsumit 10 mg.

What are the risks associated with Opsumit?

The most common side effects with Opsumit (which may affect more than 1 in 10 people) include nasopharyngitis (inflammation of the nose and throat), anaemia (low red blood cell counts) and headache. Most side effects are mild to moderate in severity. For the full list of side effects reported with Opsumit, see the package leaflet.

In animal studies, Opsumit was shown to have an adverse effect on the development of embryos. Opsumit must therefore not be used in pregnant or breastfeeding women or in women who could become pregnant and who are not using reliable contraception. Women should also not become pregnant for one month after stopping treatment.

It must also not be used in patients with severe reduction in liver function or high levels of liver enzymes in the blood. For the full list of restrictions, see the package leaflet.

Why is Opsumit authorised in the EU?

The European Medicines Agency decided that Opsumit's benefits are greater than its risks and it can be authorised for use in the EU. Opsumit has been shown to be effective in reducing illness or deaths due to PAH and the side effects reported are similar to those reported with other medicines of its class and are considered to be manageable. However, as animal studies showed an adverse effect on the development of embryos, Opsumit must never be used in pregnant women or women who could become pregnant and are not using reliable contraception.

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

The company that markets Opsumit will send educational material to patients and healthcare professionals with information on the precautions to be taken when using Opsumit. Patients' reminder cards will include a warning that the medicine must never be used in pregnant women and that women who could become pregnant must be using reliable contraception and should undergo monthly pregnancy tests.

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

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

Other information about Opsumit

Opsumit received a marketing authorisation valid throughout the EU on 20 December 2013.

Opsumit : EPAR - Medicine overview (PDF/77.53 KB)

First published: 07/02/2014
Last updated: 03/09/2018
EMA/670241/2013

Available languages (22)

Opsumit : EPAR - Risk-management-plan summary (PDF/71.49 KB)

First published: 24/06/2020
Last updated: 18/06/2021

More detail is available in the summary of product characteristics

This EPAR was last updated on 18/06/2021

Authorisation details

Product details	
Name	Opsumit
Agency product number	EMEA/H/C/002697
Active substance	Macitentan
International non-proprietary name (INN) or common name	macitentan
Therapeutic area (MeSH)	Hypertension, Pulmonary
Anatomical therapeutic chemical (ATC) code	C02KX04

Product details	
Orphan	This medicine was designated an orphan medicine. This means that it was developed for use against a rare, life-threatening or chronically debilitating condition or, for economic reasons, it would be unlikely to have been developed without incentives. For more information, see Orphan designation.

Publication details	
Marketing-authorisation holder	Janssen-Cilag International N.V.
Revision	18
Date of issue of marketing authorisation valid throughout the European Union	20/12/2013
Contact address	Janssen-Cilag International N.V. Turnhoutseweg 30 BE-2340 Beerse Belgium

Product information

22/04/2021 Opsumit - EMEA/H/C/002697 - II/0039

Opsumit : EPAR - Product information (PDF/282.37 KB)

First published: 07/02/2014
Last updated: 18/06/2021

Available languages (24)

Contents

Please note that the size of the above document can exceed 50 pages.

You are therefore advised to be selective about which sections or pages you wish to print.

Opsumit : EPAR - All authorised presentations (PDF/30.34 KB)

First published: 07/02/2014
Last updated: 09/04/2021

Available languages (24)

Opsumit : EPAR - Conditions imposed on member states for safe and effective use - Annex related to the Art. 127a (PDF/17.91 KB)

First published: 07/02/2014
Last updated: 07/02/2014

Available languages (24)

Pharmacotherapeutic group

Antihypertensives

Therapeutic indication

Opsumit, as monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III.

Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.

Assessment history

Changes since initial authorisation of medicine

Opsumit : EPAR - Procedural steps taken and scientific information after authorisation (PDF/176.05 KB)

First published: 02/10/2014
Last updated: 18/06/2021

Opsumit-H-C-2697-P46-008 : EPAR - Assessment Report (PDF/931.56 KB)

Adopted

First published: 09/10/2018
EMA/687037/2018

Opsumit-H-C-2697-P46-006 : EPAR - Assessment Report (PDF/580.22 KB)

First published: 30/11/2017
Last updated: 30/11/2017
EMA/792503/2017

Opsumit-H-C-2697-PSUV-0003 : EPAR - Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation (PDF/64.95 KB)

First published: 24/02/2015
Last updated: 24/02/2015
EMA/52026/2015

Initial marketing-authorisation documents

Opsumit : EPAR - Public assessment report (PDF/2.89 MB)

Adopted

First published: 07/02/2014
Last updated: 07/02/2014
EMA/457699/2013

CHMP summary of positive opinion for Opsumit (PDF/70.38 KB)

Adopted

First published: 25/10/2013
Last updated: 25/10/2013
EMA/CHMP/590387/2013

News

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 11-14 November 2019 (updated)
  15/11/2019
- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 21-24 October 2013
  25/10/2013

Related content

- Opsumit: Withdrawn application
- Opsumit: Paediatric investigation plan
- Opsumit: Paediatric investigation plan
- Opsumit: Orphan designation

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