EMA/706342/2011
EMEA/H/C/001218

EPAR summary for the public

Myclausen

mycophenolate mofetil

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

What is Myclausen?

Myclausen is a medicine that contains the active substance mycophenolate mofetil. It is available as tablets (500 mg) and capsules (250 mg).

Myclausen is a 'generic medicine'. This means that Myclausen is similar to a 'reference medicine' already authorised in the European Union (EU) called Cellcept. For more information on generic medicines, see the question-and-answer document here.

What is Myclausen used for?

Myclausen is used to prevent the body from rejecting a transplanted kidney, heart or liver. It is used with ciclosporin and corticosteroids (other medicines used to prevent organ rejection).

The medicine can only be obtained with a prescription.

How is Myclausen used?

Myclausen treatment should be initiated and maintained by a qualified transplant specialist.

The way that Myclausen should be given and the dose depend on the type of organ transplant.

For kidney transplants, the recommended dose in adults is 1 g twice a day by mouth starting within 72 hours after the transplant. In children aged between two and 18 years, the dose of Myclausen is calculated depending on height and weight.

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For heart transplants, the recommended adult dose is 1.5 g twice a day, starting within five days following the transplant.

For liver transplants in adults, mycophenolate mofetil should be given as an infusion (drip into a vein) for the first four days after the transplant, before the patient is switched to Myclausen 1.5 g twice a day as soon as it can be tolerated. Myclausen is not recommended for use in children after heart or liver transplants because of a lack of information on its effects in this group.

The dose may need to be adjusted in patients with liver or kidney disease. For more information, see the summary of product characteristics (also part of the EPAR).

How does Myclausen work?

The active substance in Myclausen, mycophenolate mofetil, is an immunosuppressive medicine. In the body, it is converted into mycophenolic acid, which blocks an enzyme called 'inosine monophosphate dehydrogenase'. This enzyme is important for the formation of DNA in cells, particularly in the lymphocytes (a type of white blood cell which is involved in the rejection of organ transplants). By preventing the production of new DNA, Myclausen reduces the rate at which the lymphocytes multiply. This makes them less effective at recognising and attacking the transplanted organ, lowering the risk of the organ being rejected.

How has Myclausen been studied?

Because Myclausen is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Cellcept. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefit and risk of Myclausen?

Because Myclausen is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has Myclausen been approved?

The CHMP concluded that, in accordance with EU requirements, Myclausen has been shown to have comparable quality and to be bioequivalent to Cellcept. Therefore, the CHMP's view was that, as for Cellcept, the benefit outweighs the identified risk. The Committee recommended that Myclausen be given marketing authorisation.

Other information about Myclausen:

The European Commission granted a marketing authorisation valid throughout the EU for Myclausen on 7 October 2010.

The full EPAR for Myclausen 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 Myclausen, 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 08-2011.