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CellCept

mycophenolate mofetil

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

Overview

This is a summary of the European public assessment report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach its recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the scientific discussion (also part of the EPAR).

What is CellCept?

CellCept is a medicine containing the active substance mycophenolate mofetil. It is available as capsules (250 mg), tablets (500 mg), a powder to be made up into an oral suspension (1 g / 5 ml) and a powder to be made up into a solution for infusion (drip) into a vein (500 mg).

What is CellCept used for?

CellCept 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 CellCept used?

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

The way that CellCept should be given and the dose depend on the type of organ transplant and the patient's age and size.

For kidney transplants, the recommended dose in adults is 1 g twice a day by mouth (capsules, tablets or oral suspension) starting within 72 hours after the transplant. It can also be given as an infusion lasting two hours starting within 24 hours after the transplant, for up to 14 days. In children aged between two and 18 years, the dose of CellCept is calculated depending on height and weight and should be given by mouth.

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

For liver transplants in adults, CellCept should be given as a 1-g infusion twice a day for the first four days after the transplant, before the patient is switched to 1.5 g twice a day by mouth as soon as it can be tolerated.

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 CellCept work?

The active substance in CellCept, 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, CellCept 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 CellCept been studied?

CellCept capsules and tablets have been studied in three studies involving a total of 1,493 adults following kidney transplant, in one study involving 650 adults following heart transplant and in one study involving 565 adults following liver transplant. CellCept was compared with azathioprine (another anti-rejection medicine) in all studies except for one of the kidney transplant studies, in which it was compared with placebo (a dummy treatment). A further study looked at the effect of CellCept oral suspension in 100 children following a kidney transplant. In all of the studies, all of the patients also received ciclosporin and corticosteroids, and the main measure of effectiveness was the proportion of patients whose new organ had been rejected after six months.

Further studies showed that the solution for infusion and the oral suspension produced similar levels of the active substance in the blood as the capsules.

What benefit has CellCept shown during the studies?

CellCept was as effective as azathioprine and more effective than placebo in preventing the rejection of transplanted kidneys after six months. In children undergoing kidney transplants, the rejection rates were similar to those seen in adults taking CellCept and lower than those seen in other studies of children who did not receive CellCept.

In the heart transplant study, around 38% of adult patients taking CellCept and those taking azathioprine experienced rejection after six months. Following liver transplant, 38% of the adult patients taking CellCept had rejected their new liver after six months, compared with 48% of those taking azathioprine, but the proportion of patients who had lost their new liver after a year was similar in the two groups, at around 4%.

What is the risk associated with CellCept?

The most serious risk associated with CellCept is the possible development of cancer, particularly lymphoma and skin cancer. The most common side effects with CellCept used in combination with ciclosporin and corticosteroids (seen in more than 1 patient in 10) are sepsis (blood infection), gastrointestinal candidiasis (a fungal infection of the stomach or gut), urinary tract infection (infection of the structures that carry urine), herpes simplex (a viral infection that causes cold sores), herpes zoster (a viral infection that causes chickenpox and shingles), leucopenia (low white blood cell counts), thrombocytopenia (low blood platelet counts), anaemia (low red blood cell counts), vomiting, abdominal (tummy) pain, diarrhoea and nausea (feeling sick). For the full list of side effects reported with CellCept, see the package leaflet.

It has been shown that there is a significant risk of harm to a developing baby and of miscarriage if CellCept is used in pregnancy. Therefore, CellCept must not be used during pregnancy unless there is no suitable alternative to prevent rejection of the transplant. Women able to have children should be tested before starting treatment to ensure that they are not pregnant. Both men and women must use highly effective contraception before, during and for a suitable period after CellCept treatment. Women must not breastfeed while using CellCept and patients should not donate blood or sperm during treatment or for a period afterwards. For full details of the restrictions with CellCept, see the package leaflet.

Why has CellCept been approved?

The CHMP decided that CellCept's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

The company that markets CellCept will provide educational materials for patients and healthcare professionals explaining the risk of harm to a developing baby and the precautions and measures to be taken to avoid pregnancy during treatment. There will also be very close monitoring of the outcomes of any accidentally exposed pregnancies.

Safety information has also been included in the summary of product characteristics and the package leaflet for CellCept, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about CellCept

The European Commission granted a marketing authorisation valid throughout the European Union for CellCept on 14 February 1996.

For more information about treatment with CellCept, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

CellCept : EPAR - Summary for the public (PDF/77.22 KB)

First published: 12/03/2008
Last updated: 12/01/2016

Available languages (22)

More detail is available in the summary of product characteristics

This EPAR was last updated on 20/07/2021

Authorisation details

Product details	
Name	CellCept
Agency product number	EMEA/H/C/000082
Active substance	mycophenolate mofetil
International non-proprietary name (INN) or common name	mycophenolate mofetil
Therapeutic area (MeSH)	Graft Rejection
Anatomical therapeutic chemical (ATC) code	L04AA06

Publication details	
Marketing-authorisation holder	Roche Registration GmbH
Revision	35
Date of issue of marketing authorisation valid throughout the European Union	14/02/1996
Contact address	Emil-Barell-Strasse 1 79639 Grenzach-Wyhlen Germany

Product information

25/02/2021 CellCept - EMEA/H/C/000082 - II/0161

CellCept : EPAR - Product Information (PDF/1.05 MB)

First published: 27/10/2009
Last updated: 20/07/2021

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.

CellCept : EPAR - All Authorised presentations (PDF/20.69 KB)

First published: 06/04/2006
Last updated: 06/04/2020

Available languages (24)

Pharmacotherapeutic group

Immunosuppressants

Therapeutic indication

CellCept is indicated in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants.

Assessment history

Changes since initial authorisation of medicine

CellCept : EPAR - Procedural steps taken and scientific information after authorisation (PDF/414.08 KB)

First published: 27/10/2009
Last updated: 20/07/2021

CellCept-H-C-PSUSA-00010550-201705 : EPAR - Scientific conclusions and grounds for the variation to the terms of the marketing authorisation (PDF/68.66 KB)

First published: 26/03/2018
Last updated: 26/03/2018
EMA/187794/2018

CellCept-H-C-82-P46-0034 : EPAR - Assessment Report (PDF/281.9 KB)

Adopted

First published: 22/01/2013
Last updated: 22/01/2013
EMA/735864/2012

CellCept : EPAR - Steps taken after authorisation when a cutoff date has been used (PDF/128.97 KB)

First published: 06/04/2006
Last updated: 06/04/2006

Initial marketing-authorisation documents

CellCept : EPAR - Scientific Discussion (PDF/439.78 KB)

First published: 06/04/2006
Last updated: 06/04/2006

CellCept : EPAR - Procedural steps taken before authorisation (PDF/85.09 KB)

First published: 06/04/2006
Last updated: 06/04/2006

News

- Mycophenolate: updated recommendations for contraception for men and women
  15/12/2017
- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 19-22 October 2015
  23/10/2015
- EMA recommends additional measures to prevent use of mycophenolate in pregnancy
  23/10/2015
- European Medicines Agency finalises review of medicines concerned by Roche pharmacovigilance inspection
  19/11/2013
- European Medicines Agency starts infringement procedure to investigate Roche's alleged non-compliance with pharmacovigilance obligations
  23/10/2012

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How to find us

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