

THE

CELLCEPT LEGACY

More than 15 years of clinical use...

- There have been over 8 million CellCept prescriptions in the United States since FDA approval in 1995¹
- CellCept has been cited in over 4300 publications²

Indicated for multiple organs...

- CellCept is currently approved for immunosuppression in patients receiving kidney, heart or liver transplants

A variety of formulations...

- CellCept is available in capsule, tablet, oral suspension and intravenous formulations

And a diversity of patient support...

- Genentech® Transplant Access Services helps eligible patients save on out-of-pocket prescription costs with the CellCept Coupon Card and connects patients in need to other reimbursement services and assistance programs

INDICATION

CellCept® (mycophenolate mofetil) is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants. CellCept should be used concomitantly with cyclosporine and corticosteroids.

CellCept Intravenous is an alternative dosage form to CellCept capsules, tablets and oral suspension. CellCept Intravenous should be administered within 24 hours following transplantation. CellCept Intravenous can be administered for up to 14 days; patients should be switched to oral CellCept as soon as they can tolerate oral medication.

IMPORTANT SAFETY INFORMATION

WARNING

Immunosuppression may lead to increased susceptibility to infection and possible development of lymphoma. Only physicians experienced in immunosuppressive therapy and management of renal, cardiac or hepatic transplant patients should use CellCept. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.

Female users of childbearing potential must use contraception. Use of CellCept during pregnancy is associated with increased rates of pregnancy loss and congenital malformations.

CONTRAINDICATIONS

CellCept is contraindicated in patients with a hypersensitivity to mycophenolate mofetil, mycophenolic acid or any component of the drug product. CellCept Intravenous is contraindicated in patients who are allergic to Polysorbate 80 (TWEEN).

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, or reverse side for additional Important Safety Information.

Find out more by visiting www.cellcept.com

CellCept[®]
(mycophenolate mofetil)

IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS

- Patients receiving immunosuppressive regimens involving combinations of drugs, including CellCept, as part of an immunosuppressive regimen are at increased risk of developing lymphomas and other malignancies, particularly of the skin.
- CellCept has been administered in combination with the following agents in clinical trials: antithymocyte globulin, OKT3, cyclosporine and corticosteroids. The efficacy and safety of the use of CellCept in combination with other immunosuppressive agents have not been determined.
- Oversuppression of the immune system can also increase susceptibility to infection, including opportunistic infections, fatal infections and sepsis.
- Immunosuppressed patients are at increased risk of opportunistic infections, including activation of latent viral infections. These include sometimes fatal cases of progressive multifocal leukoencephalopathy (PML) and BK virus-associated nephropathy (BKVAN).

Cases of PML have been reported in patients treated with CellCept. Hemiparesis, apathy, confusion, cognitive deficiencies and ataxia were the most frequent clinical features observed. In immunosuppressed patients with neurological symptoms, consider PML in the differential diagnosis and consult with a neurologist as clinically indicated. Consider reducing the amount of immunosuppression and be cognizant of the risk that reduced immunosuppression represents to the graft.

BKVAN is associated with serious outcomes, including deteriorating renal function and renal graft loss. Monitoring may help detect patients at risk for BKVAN. Consider reducing immunosuppression for patients who develop evidence of BKVAN.

- Teratogenic effects: Pregnancy Category D. CellCept can cause fetal harm when administered to a pregnant woman. A patient who is planning a pregnancy should not use CellCept unless she cannot be successfully treated with other immunosuppressant drugs.

Do not initiate CellCept therapy until a negative pregnancy test report is obtained within 1 week prior to beginning therapy. If this drug is used during pregnancy, apprise the patient of the potential hazard to the fetus.

Women of childbearing potential taking CellCept must receive contraceptive counseling, use effective contraception (2 reliable forms of contraception, unless abstinence is chosen) and begin using their chosen contraceptive methods 4 weeks prior to starting CellCept therapy and should continue contraceptive use during therapy and for 6 weeks after stopping CellCept.

- Monitor patients for neutropenia. If neutropenia develops [absolute neutrophil count (ANC) $<1.3 \times 10^3/\mu\text{L}$], dosing with CellCept should be interrupted or the dose reduced, appropriate diagnostic tests performed and the patient managed appropriately.
- Cases of pure red cell aplasia (PRCA) have been reported in patients treated with CellCept in combination with other immunosuppressive agents.
- **CAUTION: NEVER ADMINISTER CELLCEPT INTRAVENOUS SOLUTION BY RAPID OR BOLUS INTRAVENOUS INJECTION.**

PRECAUTIONS

- Gastrointestinal bleeding (requiring hospitalization) has been observed.
- During treatment with CellCept, avoid the use of live attenuated vaccines and advise patients that vaccinations may be less effective.
- Care should be taken if CellCept Oral Suspension is administered to patients with phenylketonuria.

ADVERSE REACTIONS

- The principal adverse reactions associated with the administration of CellCept include diarrhea, leukopenia, sepsis, vomiting, and there is evidence of a higher frequency of certain types of infections, eg, opportunistic infections (see **WARNINGS** in full Prescribing Information). Phlebitis and thrombosis have been reported with intravenous administration. Please refer to the full Prescribing Information for additional **ADVERSE REACTIONS**.

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

References: 1. IMS Health. Dispensed TRX: CellCept. 1995-2008. 2. <http://www.ncbi.nlm.nih.gov/sites/entrez>. PubMed search user query terms were "(mycophenolate mofetil [Title/Abstract] OR (MMF [Title/Abstract] AND transplant [Title/Abstract]) OR cellcept [Title/Abstract] NOT (letter [Publication Type] OR editorial [Publication Type]) NOT 2011 [All Fields] NOT 2010 [All Fields] NOT December 2009 [Title/Abstract] NOT November 2009 [Title/Abstract] NOT October 2009 [Title/Abstract] NOT September 2009 [Title/Abstract] NOT August 2009 [Title/Abstract] NOT July 2009 [Title/Abstract] NOT June 2009 [Title/Abstract] NOT May 2009 [Title/Abstract])."

Genentech
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(mycophenolate mofetil)