

**IMPORTANT
CORRECTION
OF DRUG
INFORMATION**

May 2015

Subject: Correction of labeling provided with CellCept® Intravenous (mycophenolate mofetil hydrochloride for injection) and CellCept® Oral Suspension (mycophenolate mofetil for oral suspension).

Dear Healthcare Provider:

Genentech has recently become aware that the US package inserts packaged with CellCept® Intravenous and CellCept® Oral Suspension are not up-to-date; the package inserts are missing updates to important safety information found in the current version of the package insert. CellCept® 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; the full indication is included below.

CellCept® is available in four formulations. The missing updates only affect the package inserts packaged with the Intravenous (IV) and Oral Suspension products; the package inserts packed with CellCept® capsules and tablets are current. The package inserts posted on the on-line sources gene.com, cellcept.com, and mycophenolateREMS.com are all current.

The updates missing from the package inserts packaged with CellCept® IV and CellCept® Oral Suspension are the following:

- **WARNINGS and BOXED WARNING: Embryofetal Toxicity, Pregnancy Exposure Prevention and Planning and PRECAUTIONS: Pregnancy Testing**

Revisions were made to the existing Boxed Warning and Warning language on pregnancy prevention in order to strengthen the risk language and to include the recommendation for two pregnancy tests (one immediately before taking CellCept® and one 8-10 days later), rather than the single test previously recommended.

- **WARNINGS: New or Reactivated Viral Infections:**

Revision of existing warning about susceptibility to infection, to include information on reactivation of specific viral infections including hepatitis B and C, and CMV virus.

- **PRECAUTIONS: Drug Interactions: Proton Pump Inhibitors (PPIs)**

Concentrations of mycophenolic acid (MPA) were reduced after coadministration of single doses of proton pump inhibitors, possibly due to decreased solubility of MPA at increased gastric pH.

Prescriber Action:

Because these updates are missing from the information that your patients may have received when they filled their prescriptions, **it is important that you:**

- Remind your patients to discuss with you all other medicines and supplements that they may be taking.
- Ensure that your patients understand that you will perform a pregnancy test before they begin treatment, after 8-10 days, and periodically while they are taking CellCept®. They need to be aware of the risks to any pregnancy, most notably the risk of fetal malformations and early pregnancy loss, and they need to use effective birth control while taking CellCept® and for six weeks after stopping CellCept®.
- Remind your patients to discuss with you any medical history of viral infections such as shingles, herpes infections, CMV, BK virus, or hepatitis B or C, and ensure that they understand that these infections could become active again while they are taking CellCept®.

Indications for CellCept®:

CellCept® 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.

This letter is not intended as a complete description of the benefits and risks related to the use of CellCept®. Please refer to the attached full prescribing information and medication guide. For more information on the pregnancy risks associated with CellCept® please visit mycophenolateREMS.com. To report a pregnancy to the Mycophenolate Pregnancy Registry, please call 1-800-617-8191.

You may also contact our Medical Communications department at 1-800-821-8590 if you have any questions about the information contained in this letter or the safe and effective use of CellCept®. The current prescribing information is also available on gene.com.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients taking CellCept® to Genentech at 1-888-835-2555. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

Sincerely,



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