Genentech
A Member of the Roche Group

September 2025

Subject: Serious Risk with Use of CELLCEPT (mycophenolate mofetil): Anaphylaxis and Angioedema

Dear Health Care Provider:

The purpose of this letter is to inform you of important safety information for CELLCEPT (mycophenolate mofetil), indicated for the prophylaxis of organ rejection, in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart or liver transplants, in combination with other immunosuppressants.

Serious Risks With Use of CELLCEPT

- Postmarketing cases of hypersensitivity reactions, including angioedema and anaphylaxis, have been reported with CELLCEPT.
- Anaphylactic reaction is a new important identified risk for CELLCEPT. Health care professionals need to be aware of the full range of signs and symptoms of anaphylactic reaction and the appropriate medical treatment. Discontinue use of CELLCEPT permanently if an anaphylactic reaction occurs.
- The Contraindications and Warnings and Precautions sections of the prescribing information have been updated to reflect this risk.

CELLCEPT is contraindicated in patients with a history of hypersensitivity, including anaphylaxis, to mycophenolate mofetil (MMF), mycophenolic acid (MPA) or any component of the drug product.

Anaphylaxis is a severe, potentially fatal, systemic allergic reaction that occurs suddenly after contact with an allergy-causing substance.

Cases of anaphylaxis and angioedema have been reported with CELLCEPT. These reactions generally occurred within hours to the next day after initiating CELLCEPT. Symptoms included swelling of face, lips, tongue, or throat, difficulty breathing or swallowing, chest pain, and dizziness. A few cases were reported with positive rechallenge and / or positive dechallenge. The reporting rate for anaphylactic reaction observed from CELLCEPT postmarketing safety data is 0.98 per 100,000 patient years.

Prescriber Action

- Treating physicians need to be aware of the full range of signs and symptoms of anaphylaxis and angioedema and the appropriate medical treatment. These reactions generally occurred within hours to the next day after initiating CELLCEPT. If signs or symptoms of a hypersensitivity reaction occur, discontinue CELLCEPT; treat and monitor until signs and symptoms resolve.
- Inform patients of the potential risk of hypersensitivity reactions, including angioedema and anaphylaxis. Advise patients to stop taking CELLCEPT and seek immediate medical attention if signs or symptoms of a hypersensitivity reaction occur (such as swelling of face, lips, tongue, or throat; difficulty breathing or swallowing).
- Advise patients to discontinue CELLCEPT if the signs and symptoms of hypersensitivity reaction appear.

Reporting Adverse Events / Product Complaints and Company Contact

Health Care Providers should report any adverse events suspected to be associated with the use of CELLCEPT to Genentech at 1-888-835-2555. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Please report any product complaint suspected to be associated with the use of CELLCEPT to Genentech at (800) 334-0290.

Should you have any questions about the information in this letter or the safe and effective use of CELLCEPT, please feel free to contact us at: Genentech Medical Communications Department at (800) 821-8590.

This letter is not intended as a complete description of the benefits and risks related to the use of CELLCEPT. Please refer to the enclosed full prescribing information and medication guide.

Sincerely,

Beatriz Perez

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