July, 2025

CellCept (Mycophenolate mofetil), new important identified risk- Update to Contraindications and New Warnings and precautions: Anaphylactic reaction

Dear Healthcare professional,
Roche Servicios S.A. would like to inform you of the following:

Summary

- From post-marketing data, cases of anaphylaxis, anaphylactic reaction, anaphylactic shock and anaphylactoid reaction for CellCept [Mycophenolate mofetil-(MMF)] were identified.
- Anaphylactic reaction is a new important identified risk for CellCept (MMF). 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 MMF permanently if an anaphylactic reaction occurs.
  Information on this new risk will be updated in the product information of CellCept (MMF).

Background on the safety concern

CellCept in combination with corticosteroids and either cyclosporine (CsA) or tacrolimus (TRL) is indicated for prophylaxis of acute organ rejection in adult and pediatric patients and treatment of first or refractory organ rejection in adult patients receiving allogeneic renal transplants, cardiac transplants and hepatic transplants. In addition, MMF is indicated for induction and maintenance therapy of adult and paediatric patients with Class III-V lupus nephritis (LN).

Anaphylaxis, a type I hypersensitivity reaction is an acute, potentially fatal systemic allergic reaction with varied mechanisms and clinical presentations.

Cases of anaphylaxis, anaphylactic reaction, anaphylactic shock and anaphylactoid reaction have been reported with CellCept (MMF). The reactions generally occurred within a few minutes to a day after dosing. 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 (MMF) post marketing safety data is 0.98 per 100,000 patient years.

Treating physicians need to be aware of the full range of signs and symptoms of anaphylactic reaction and the appropriate medical treatment.

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

It is recommended:

- At the first signs or symptoms of an anaphylactic reaction, advise patients to seek immediate medical attention (signs and symptoms include, but are not limited to, swelling of face, lips, tongue, or throat; difficulty breathing or swallowing, chest pain, dizziness, palpitation, rash, hives, itching, and lightheadedness)
- Advise patients to discontinue CellCept(MMF) permanently if the signs and symptoms of anaphylactic reaction appear.

Roche is working closely with health authorities to update the product label to reflect the risk of anaphylactic reaction, which will include an update to the Warnings and Precautions and Contraindications sections.

This DHPC has been disseminated in advance of the company label update to make you aware of the identified risk and to facilitate prompt management of the risk.

Call for reporting

Health care professionals should report any adverse events suspected to be associated with the use of CellCept ® (Mycophenolate Mofetil) to: cac.farmacovigilancia@roche.com

Company contact point

Should you have any questions regarding the use of CellCept ® (Mycophenolate Mofetil), please feel free to contact us at cac.medical_info@roche.com

Yours sincerely,

Dr. Juan Carlos Quesada

Patient Safety Lead

Roche Servicios S.A.

Dr. Carlos Sandoval

Medical Director

Roche Servicios S.A.