21 July 2025

CellCept® (mycophenolate mofetil)
New important identified risk: anaphylactic reaction
Update to Contraindications and New Warnings and Precautions

Dear Healthcare Professional,

Roche Products (New Zealand), in agreement with Medsafe, 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. Healthcare 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.
- Information on this new risk will be updated in the New Zealand Data Sheet of CellCept.

Background on the safety concern

CellCept is indicated for the prophylaxis of solid organ rejection in adults receiving allogeneic organ transplants. CellCept is also indicated for the prophylaxis of organ rejection in paediatric patients (2 to 18 years) receiving allogeneic renal transplants.

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 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

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mycophenolate mofetil, mycophenolic acid or any component of the drug product. CellCept intravenous (IV) solution is also contraindicated in people with known hypersensitivity to polysorbate 80. Refer to the CellCept Data Sheet for a full list of contraindications.

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 permanently if the signs and symptoms of anaphylactic reaction appear.

Roche is working closely with Medsafe to update the New Zealand Data Sheet to reflect the risk of anaphylactic reaction, which will include an update to the *Contraindications* and *Special Warnings And Precautions For Use* sections.

This Dear Healthcare Professional Communication has been disseminated in advance of the Data Sheet update to make you aware of the identified risk and to facilitate prompt management of the risk. Before prescribing, please review the full CellCept Data Sheet available at www.medsafe.govt.nz.

Reporting Adverse Events

Roche will continue to monitor the safety of CellCept through established reporting mechanisms and notify regulatory authorities as per current regulations. Please report any suspected adverse events via email to Roche Patient Safety at nz.drugsafety@roche.com. Alternatively, this information may be reported to Medsafe at https://www.medsafe.govt.nz/safety/report-a-problem.asp.

Further Information

If you have any questions or require additional information regarding the use of CellCept, to report an adverse event (side effect) or product quality defect or to submit a temperature excursion assessment, please visit MedInfo.roche.com or phone 0800 276 243.

Yours sincerely,

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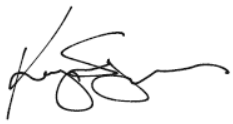

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