6th August 2026

CellCept® (mycophenolate mofetil): Extension to post-treatment contraception period for women of childbearing potential from 6 weeks to 6 months

Dear Healthcare Professional,

Roche Products (New Zealand), following consultation with Medsafe, would like to inform you of the following:

Summary

- Mycophenolate mofetil (CellCept) is a potent human teratogen, associated with a high risk of spontaneous abortions and congenital malformations when used during pregnancy.
- CellCept is contraindicated in women of childbearing potential not using highly effective contraceptive methods
- The duration for which women of childbearing potential must use effective contraception after discontinuation of CellCept is being **extended from 6 weeks to 6 months**
- This update is not based on new safety data. It is a proactive measure to align with international regulatory recommendations for genotoxic medicinal products.
- Healthcare professionals should ensure patients are fully informed of the risks and adhere to updated contraception requirements.

Background on the safety concern

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

CellCept is contraindicated:

- during pregnancy due to its mutagenic and teratogenic potential
- in women of childbearing potential not using highly effective contraceptive methods
- in women who are breastfeeding

Rationale for the updated recommendation:

The following malformations were most frequently reported post-marketing, in children of patients exposed to mycophenolate mofetil in combination with other immunosuppressants during pregnancy:

- Facial malformations such as cleft lip, cleft palate, micrognathia and hypertelorism of the orbits;
- Abnormalities of the ear (e.g. abnormally formed or absent external/middle ear) and eye (e.g. coloboma, microphthalmos);
- Malformations of the fingers (e.g. polydactyly, syndactyly, brachydactyly);
- Cardiac abnormalities such as atrial and ventricular septal defects;
- Oesophageal malformations (e.g. oesophageal atresia);
- Nervous system malformations (such as spina bifida).

Based on a comprehensive review of current regulatory guidance and scientific best practices, the recommended duration of post-treatment contraception for women of childbearing potential has been

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extended from 6 weeks to 6 months. The 6-month duration was determined in accordance with updated international regulatory recommendations[1,2,3] for medicinal products with genotoxic potential. The recommendation takes into account both drug elimination and the maturation cycle of human oocytes, providing a conservative and harmonised approach to minimising the potential risk of embryo-fetal exposure from oocytes affected during treatment. This update aims to ensure continued protection against potential embryo-fetal exposure and to harmonise CellCept prescribing information with current global standards.

Guidelines for patients:

- Before the start of treatment, women of child bearing potential must be made aware of the increased risk of pregnancy loss and congenital malformations and must be counselled regarding pregnancy prevention, and planning.
- Women of child bearing potential must use two reliable forms of contraception simultaneously, at least one of which must be highly effective, before beginning CellCept therapy, during therapy, and for **6 months following discontinuation** of therapy, unless abstinence is the chosen method of contraception

Healthcare professionals should ensure that patients are fully informed of the teratogenic risks associated with mycophenolate and the updated contraception requirements.

New Safety Information will be added to the Data Sheet

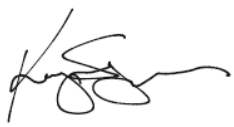
Roche is working closely with Medsafe to update the New Zealand Data Sheet with the new contraception requirements. This Dear Healthcare Professional Communication has been disseminated in advance of the Data Sheet update to make you aware of the updated post treatment contraception requirements. Before prescribing, please review the full CellCept Data Sheet available at www.medsafe.govt.nz.

Further Information and Reporting Adverse Events

Roche will continue to monitor the safety of CellCept through established reporting mechanisms and notify regulatory authorities as per current regulations. 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.

Alternatively, adverse events information may be reported to the Centre for Adverse Reactions Monitoring (CARM)/Medsafe at https://pophealth.my.site.com/carmreportnz/s/.

Yours sincerely,
On behalf of Roche Products (New Zealand) Limited



Dr Kerryn Symons
Country Medical Director

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[1] European Medicines Agency (EMA), Committee for Medicinal Products for Human Use (CHMP), 2023. NcWP/SWP recommendations on the duration of contraception following the end of treatment with a genotoxic drug, EMA/CHMP/SWP/74077/2020 rev. 1. Amsterdam: European Medicines Agency.

[2] U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), 2019. Oncology pharmaceuticals: Reproductive toxicity testing and labeling recommendations: Guidance for industry. Silver Spring, MD: U.S. Department of Health and Human Services.

[3] Bowman, C.J., Becourt-Lhote, N., Boulifard, V., Cordts, et al., 2023. Science-based approach to harmonize contraception recommendations in clinical trials and pharmaceutical labels. Clinical Pharmacology & Therapeutics, 113(2), pp. 226–245.