Direct Healthcare Professional Communication

August 2026

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

Dear Healthcare Professional,

Roche Egypt in agreement with the General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at the Egyptian Drug Authority 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.
- Updated recommendation: Women of childbearing potential must use effective contraception during treatment and for 6 months after discontinuation of CellCept (previously 6 weeks).
- This update 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

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).

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

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).

Rationale for the updated recommendation: 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 extended from 6 weeks to 6 months.** The 6-month duration was determined in accordance with updated EMA SWP/NcWP recommendations 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 harmonized approach to minimizing the potential risk of embryo-fetal exposure from oocytes affected during treatment. This change is driven by proactive alignment with updated international regulatory recommendations for genotoxic medicinal products, guidance from the EMA Safety Working Party and FDA, as well as emerging scientific consensus, supporting more conservative contraception durations to ensure an adequate safety margin, considering drug elimination and the human reproductive cycle. This update aims to ensure continued protection against potential embryo-fetal exposure and to harmonise CellCept prescribing information with current global standards.
Women of childbearing potential:

- Before the start of treatment, must be made aware of the increased risk of pregnancy loss and congenital malformations and must be counseled regarding pregnancy prevention, and planning.
- Must use at least one highly effective method of contraception, preferably combined with an additional method,
  - before starting treatment,
  - during treatment,
  - and for 6 months after discontinuation

Healthcare professionals should ensure that patients are fully informed of the teratogenic risks associated with mycophenolate and the updated contraception requirements. This update is reflected in the product information and will reflect in associated risk minimisation materials.

References

Medsafe (New Zealand): https://www.medsafe.govt.nz/safety/DHCPLetters/CellCeptAugust2026.pdf
Singapore HAS : https://www.hsa.gov.sg/announcements/cellcept-mycophenolate-mofetil-update-to-post-treatment-contraception-period-for-women-of-childbearing-potential-extension-from-6-weeks-to-6-months/

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:
Name: General Administration for Pharmaceutical Vigilance
Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt,
Email: pv.followup@edaegypt.gov.eg
Online reporting: : https://vigiflow-eforms.who-umc.org/eg/med
QR Code:
Hotline: 15301