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(來函請敘明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

14 Aug 2026

Dear Healthcare Professionals,

CellCept® (mycophenolate mofetil): Update to Post-treatment Contraception Period for Women of Childbearing Potential (Extension from 6 weeks to 6 months)

Your attention is drawn to the following Singapore Health Sciences Authority's (HSA) announcement that a Dear Healthcare Professional Letter has been issued by Roche Singapore Pte Ltd to update healthcare professionals that the recommended duration of post-treatment contraception with Cellcept® for women of childbearing potential has been extended from 6 weeks to 6 months.

This update follows a review of current regulatory guidance and scientific best practices, with the 6-month duration determined in accordance with updated EMA's recommendations for medicinal products with genotoxic potential. The recommendation takes into account both drug elimination and the maturation cycle of human oocytes to minimise the potential risk of embryo-fetal exposure. Healthcare professionals are advised to ensure that women of childbearing potential are counselled on the increased risk of pregnancy loss and congenital malformations before starting treatment, and that they use two reliable forms of contraception simultaneously before, during, and for 6 months after discontinuation of treatment. This information will be updated in the product information and in associated risk minimisation materials.

Cellcept is indicated for prophylaxis of acute organ rejection and treatment of refractory organ rejection in patients receiving allogeneic renal transplants; prophylaxis of acute organ rejection and increased graft and patient survival in patients receiving allogeneic cardiac transplants; and prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplants.

Please refer to the following website in HSA for details:
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/

In Hong Kong, there are 34 registered pharmaceutical products containing mycophenolate mofetil or mycophenolic acid. All products are prescription only medicines. Related news on the teratogenic risk and contraception advice was issued by various drug regulatory authorities, and was posted on the Drug Office website since 24 Oct 2015, with the latest update posted on 7 Feb 2018. Letters to inform local healthcare professionals were issued on 26 October 2015. In Dec 2016, the Registration Committee of the Pharmacy and Poisons Board of Hong Kong (the Registration Committee) discussed the teratogenic risk of mycophenolate mofetil and related drugs, and decided that the sales pack and/or package insert of the products should include the relevant safety information.

So far, the Department of Health (DH) has received 97 cases of adverse drug reaction with regard to mycophenolate mofetil or mycophenolic acid, of which one case was reported as missed abortion after taking the drug. In light of the above HSA's announcement on the update of post-treatment contraception period from 6 weeks to 6 months, the matter will be discussed by the Registration Committee.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Clive CHAN)
for Assistant Director (Drug)