

衛生署藥物辦公室
藥物資訊及警戒科

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DEPARTMENT OF HEALTH
DRUG OFFICE

DRUG INFORMATION AND
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Dear Healthcare Professionals,

Update to Singapore package insert of Prostin E2 Vaginal Tablet (dinoprostone)

Your attention is drawn to the Health Sciences Authority's (HSA) announcement that a Dear Healthcare Professional Letter has been issued by Pfizer Pte Ltd to inform healthcare professionals that the package insert of Prostin E2 Vaginal Tablet (dinoprostone) have been updated to strengthen the risk minimisation measures to manage the known risk of foetal and neonatal death associated with uterine hyperstimulation and uterine rupture.

The new safety information includes a statement to restrict usage to qualified healthcare professionals and hospitals and clinics with specialised obstetric units that have facilities for continuous monitoring. Other information includes warnings against exceeding the maximum recommended dose or shortening the dosing interval, advice to consider concomitant medicine as well as maternal or foetal status, and documentation of this safety issue in the package insert.

Please refer to the following website in HSA for details:

<https://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/update-to-singapore-package-insert-of-prostin-e2-vaginal-tablet>

In Hong Kong, there are 2 registered pharmaceutical products containing dinoprostone which are vaginal tablets/pessaries, namely Prostin E2 Vag Tab 3mg (HK-19734) registered by Pfizer Corporation Hong Kong Limited; and Propess Vaginal Pessaries 10mg (HK-41119) registered by Ferring Pharmaceuticals Ltd. Both products are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to dinoprostone. The DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

*We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority*

Please report any adverse events caused by drugs to the Adverse Drug Reaction 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,



(Ling PANG)

for Assistant Director (Drug)