衞生署藥物辦公室
藥物資訊及進出口管制科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG INFORMATION AND
IMPORT/EXPORT CONTROL DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong

電話號碼 Tel. No.: (852) 3974 4175
詢問處 Enquiries (852) 3974 4175
傳真號碼 Faxline No.: (852) 2803 4962
本署檔號 OUR REF.:
(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

16 Jan 2026

Dear Healthcare Professionals,

Xtandi™ (enzalutamide) Interference with Laboratory Test CMIA leading to Falsely Elevated Digoxin Plasma Levels

Your attention is drawn to the following Singapore Health Sciences Authority's (HSA) announcement that a Dear Healthcare Professional Letter has been issued by Astellas Pharma Singapore Pte. Ltd. to inform healthcare professionals that Xtandi™ (enzalutamide) may interfere with the chemiluminescent microparticle immunoassay (CMIA) laboratory test method. This interference can lead to falsely elevated digoxin plasma level results in patients taking enzalutamide, regardless of whether the patient is actually taking digoxin.

Healthcare professionals are advised to confirm the serum digoxin levels using another type of assay before determining the need for discontinuation or dose adjustments of digoxin in patients taking enzalutamide. Enzalutamide may also inhibit the efflux transporter P-glycoprotein (P-gp), leading to increased serum levels of digoxin, a P-gp substrate. Digoxin should therefore be used with caution when administered concomitantly with enzalutamide and may require dose adjustment to maintain optimal plasma concentrations.

Please refer to the following website in HSA for details:
https://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/xtandi--(enzalutamide)-interference-with-laboratory-test-cmia-leading-to-falsely-elevated-digoxin-plasma-levels

In Hong Kong, there are 4 registered pharmaceutical products containing enzalutamide. They are prescription-only medicines. Enzalutamide is used in the treatment of metastatic castration-resistant prostate cancer. So far, the Department of Health (DH) has received 22 cases of adverse drug reaction reports related to enzalutamide, but these cases were not related to interference with CMIA laboratory test results of digoxin. In light of the above HSA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

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)