衞生署藥物辦公室
藥物資訊及警戒科
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 PHARMACOVIGILANCE 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.: 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.)

3 Oct 2023

Dear Healthcare Professionals,

New safety information for Omega-3-acid ethyl esters

Your attention is drawn to the European Medicines Agency's (EMA) announcement that the Pharmacovigilance Risk Assessment Committee (PRAC) agreed to add atrial fibrillation (irregular, rapid contraction of the heart) as a common side effect to the product information for medicines containing omega-3-acid ethyl esters.

These medicines are indicated for the treatment of hypertriglyceridaemia, when a modification of diet and lifestyle alone are not sufficient to bring down levels of triglyceride, a type of fat, in the blood. Hypertriglyceridemia is a risk factor for coronary artery disease. Patients on these medications often have other conditions such as cardiovascular diseases and diabetes.

During a Periodic Safety Update Single Assessment procedure, the PRAC considered systematic reviews and meta-analyses of randomised controlled clinical trials which highlighted a dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors treated with omega-3-acid ethyl esters compared to placebo. The observed risk is highest with a dose of 4 g daily. If atrial fibrillation develops, treatment should be permanently discontinued.

The PRAC agreed to recommend an update to the product information to inform healthcare professionals and patients of the risk of atrial fibrillation. A Direct Healthcare Professional Communication (DHPC) will be sent shortly to provide doctors with further details. Once adopted, this DHPC will be forwarded to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh). Following the CMDh opinion, the DHPC will be disseminated to healthcare professionals by the marketing authorisation holder, according to an agreed communication plan, and published on the DHPCs page and in national registers in European Union Member States.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-25-28-september-2023

In Hong Kong, there is one registered pharmaceutical product containing omega-3-acid ethyl esters, namely Omacor Capsules 1000mg (HK-66442). The product is registered by Lee's Pharmaceutical (HK) Limited. It is a prescription-only medicine. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to omega-3-acid ethyl esters. In light of the above EMA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

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 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,

(Sheila CHUNG)
for Assistant Director (Drug)