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

15 Jan 2022

Dear Healthcare Professionals,

Mavenclad (Cladribine): risk of serious liver injury

Your attention is drawn to the European Medicines Agency's (EMA) announcement that the Pharmacovigilance Risk Assessment Committee (PRAC) discussed a direct healthcare professional communication (DHPC) containing important safety information for Mavenclad. That DHPC aims to inform healthcare professionals about adverse events of liver injury with Mavenclad (cladribine), and gives new recommendations about liver function monitoring.

Mavenclad is a medicine used to treat adults with the relapsing forms (repeated flare-ups of the symptoms) of multiple sclerosis, a disease in which inflammation damages the protective sheath around the nerve cells in the brain and spinal cord (demyelination). Mavenclad is used in patients whose disease is highly active.

Liver injury, including serious cases and cases leading to discontinuation of treatment, has been reported in patients treated with Mavenclad. A recent review of available safety data has concluded on an increased risk for liver injury following treatment with Mavenclad. Most patients who experienced liver injury had mild clinical symptoms. However, in some cases, transitory high levels of enzyme transaminase exceeding 1000 units per litre and jaundice (liver affection causing, amongst others, yellowing of the skin and eyes) were described.

Liver injury will be included in the product information of Mavenclad as an adverse drug reaction of uncommon frequency.

Healthcare professionals are advised to perform a detailed review of patient history of underlying liver disorders or episodes of liver injury with other medicines before initiating patient treatment. During treatment, liver function tests should be conducted, and repeated as necessary. In case a patient develops liver injury, treatment with Mavenclad should be interrupted or discontinued, as appropriate.

Patients should be advised to report immediately to their healthcare professional any signs or symptoms of liver injury. Healthcare professionals are asked to report any suspected adverse reactions via their national reporting system. Reporting suspected adverse reactions after authorisation of the medicinal product is important to ensure patient safety.

According to the announcement, DHPC for Mavenclad will be forwarded to EMA's Committee for Medicinal Products for Human Use (CHMP) for decision before dissemination to healthcare professionals by the marketing authorization holder.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-10-13-january-2022

In Hong Kong, there is 1 registered pharmaceutical product containing cladribine. The product is a prescription-only medicine. So far, the Department of Health (DH) has not received cases of adverse drug reaction related to cladribine. In light of the above EMA's announcement, the DH will remain vigilant on safety update of the drug issued by the EMA and other overseas drug regulatory authorities and consider if any further action deemed necessary.

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,

(Terence MAN)
for Assistant Director (Drug)