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(IN REPLY PLEASE QUOTE THIS FILE REF.)

1 Mar 2022

Dear Healthcare Professionals,

Donepezil and cardiac conduction disorders

Your attention is drawn to the Therapeutic Goods Administration's (TGA) announcement that cardiac conduction disorders have been reported in patients receiving donepezil. The Product Information (PI) documents for this medicine are being updated to advise caution in patients with known QTc prolongation or a family history of this condition. Additionally, caution is advised in patients also receiving other drugs that affect the QTc interval, or who have certain types of cardiac disease or electrolyte disturbances. As these adverse effects can be severe and potentially life threatening, clinical monitoring may be required.

Donepezil is marketed in Australia as Aricept and various generic brands. The following warning has been added to 'Cardiovascular conditions' in the 'Special warnings and precautions for use' section (4.4) of the Aricept PI for donepezil:

- 'Cases of QTc interval prolongation and Torsades de Pointes have been reported for donepezil (see sections 4.4 and 4.8). Caution is advised when donepezil is used in combination with other medicinal products known to prolong the QTc interval and clinical monitoring may be required. Examples include: Class IA antiarrhythmics (e.g. disopyramide); Class III antiarrhythmics (e.g. amiodarone, sotalol); Certain antidepressants (e.g. citalopram, escitalopram, amitriptyline); Other antipsychotics (e.g. phenothiazine derivatives, pimozide, ziprasidone); Certain antibiotics (e.g. clarithromycin, erythromycin, moxifloxacin)'

In the 'Adverse effects' section (4.8) of the Aricept PI for donepezil, 'electrocardiogram QT interval prolonged' and 'polymorphic ventricular tachycardia including Torsades de Pointes' have been added to the post-marketing experience list.

The PI updates are based on evidence published in the literature and from post-market adverse event data in Australia and internationally. To 5 Jan 2022, there have been 18 cases of atrioventricular block,

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atrioventricular block complete, atrioventricular block second degree, bundle branch block, bifascicular block or Torsades de Pointes associated with donepezil reported to the TGA and included in its Database of Adverse Event Notifications.

Health professionals should be aware of any pre-existing or family history of cardiac disease, significant electrolyte changes and relevant drug interactions when prescribing donepezil for a patient. The cardiac conduction disorders caused by donepezil can be potentially life threatening, so monitoring of cardiac function may be required in at-risk individuals or where this adverse event is suspected.

Please refer to the following website in TGA for details:

<https://www.tga.gov.au/publication-issue/donepezil-and-cardiac-conduction-disorders>

In Hong Kong, there are 37 registered pharmaceutical products containing donepezil. All products are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to donepezil. In light of the above TGA'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,



(Terence MAN)

for Assistant Director (Drug)