The Arab Republic of Egypt Egyptian Drug Authority

Central Administration for Pharmaceutical Care

General Administration for Pharmaceutical Vigilance



جمهورية مصر العربية هيئة الدواء المصرية الإدارة المركزية للرعاية الصيدلية الإدارة العامة لليقظة الصيدلية

Direct Healthcare Professional Communication

July 2022

Citalopram and Escitalopram – Reminder of Risk of Dose Dependent QT interval Prolongation

Dear Healthcare Professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary:

- The dose-dependent risk of prolongation of the QT interval maximum dosages are as follows:
 - <u>Citalopram:</u> 40 mg per day in adults, and 20 mg per day in patients aged over 65 and/or with hepatic impairment
 - <u>Escitalopram:</u> 20 mg per day in adults and 10 mg per day in patients aged over 65 and/or with hepatic impairment
- Contraindications
 - In combination with other medicinal products known to induce prolongation of QT interval including:
 - class IA and III antiarrhythmics
 - > antipsychotics and tricyclic antidepressants
 - certain anti-microbial agents (example: sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatments in particular halofantrine),
 - certain antihistamines (astemizole, hydroxyzine, mizolastine)
 - In patients with acquired or congenital prolongation of the QT interval
- They should be used with caution in patients at risk, especially those with:
 - significant bradycardia
 - o recent acute myocardial infarction
 - o unstable heart failure
- It is necessary to correct electrolyte abnormalities before starting treatment (hypokalaemia or hypomagnesemia which increase the risk of arrhythmia)

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Background on the safety concern

From 2011, the SPCs for Citalopram and Escitalopram were amended to include the risk of dosedependent prolongation of the QT interval, and consequently a reduction in the maximum authorized doses, in particular in elderly subject, as well as new contraindications and precautions for use.

In 2019, the study conducted in France by Chastang et al. assessed the prevalence and impact of interventions by pharmacists following the combination of citalopram or escitalopram with other medicinal products known to induce prolongation of the QT interval. This study concludes that a high number of hospital prescriptions for citalopram or escitalopram presents a contraindicated combination with other drugs known to induce prolongation of the QT interval. The classes of drugs most frequently found were: antiarrhythmics (amiodarone, sotalol), antipsychotics (haloperidol, cyamemazine, amisulpride, chlorpromazine, tiapride) and antiemetics (droperidol) which can cause Torsades de Pointes if combined with citalopram or 'escitalopram.

References

France

https://ansm.sante.fr/informations-de-securite/citalopram-et-escitalopram-seropram-seroplex-generiquesrappel-sur-le-risque-dallongement-dose-dependant-de-lintervalle-qt

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451 Telephone: +202-25354100, Extension: 1470 Fax: +202 – 23610497

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG QR Code:

Hotline: 15301



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