General Administration for

Pharmaceutical Vigilance





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

Direct Healthcare Professional Communication

December 2021

Voriconazole – Risk of drug-drug interaction with Lurasidone since it may result in significant increase in Lurasidone exposure

Dear Healthcare Professional,

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

Summary:

- Voriconazole increases levels of Lurasidone, as the metabolism of Lurasidone can be decreasedwhen combined with Voriconazole.
- Coadministration of voriconazole with lurasidone is contraindicated since significant increases inlurasidone exposure have the potential for serious adverse reactions.

Further information on the safety concerns:

Voriconazole is a strong inhibitor of the hepatic enzyme CYP3A4 and Lurasidone is predominantly metabolized by CYP3A4. Therefore Voriconazole can patients' exposure to Lurasidone.

Lurasidone should not be used concomitantly with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, etc.) or strong CYP3A4 inducers (e.g., rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine, etc.).

Interaction between Voriconazole and Lurasidone may be manifested as fever, stiff muscles, falls, confusion, changes in heart rate/blood pressure, sweating, muscle pain, weakness or tremors, uncontrollable movements of the face/tongue/other body parts, light-headedness or faintness when rising from a sitting position.

Reminder of the therapeutic indications for Conazoglob:

Voriconazole is Conazoglob is a broad-spectrum, triazole antifungal agent and is indicated in adults and children aged 2 years and above as follows:

Treatment of invasive aspergillosis.
Treatment of candidaemia in non-neutropenic patients.
Treatment of fluconazole-resistant serious invasive Candida infections (including C.krusei). Treatment of serious fungal infections caused by Scedosporium spp. and Fusarium spp.
Conazoglob should be administered primarily to patients with progressive, possibly life-threatening infections.

OF:CAP.Care.001.01 Issue/Rev no.: 1/0 Issue Date: 30/09/2021 Rev Date:.../.../ Page 1 of 2







Tel.: 237484988

Ext.:1470

General Administration for Pharmaceutical Vigilance





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

 \bot Prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem celltransplant (HSCT) recipients.

Recommendations for Healthcare Professionals:

- All concomitant drugs should be checked with the patient before prescribing Conazoglob.
- Lurasidone should not be used concomitantly with strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, etc.) or strong CYP3A4 inducers (e.g., rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine, etc.)

References

FDA https://www.accessdata.fda.gov/drugsatfda docs/label/2022/208562s006lbl.pdf

Call for reporting

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

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

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

QR Code:

Hotline: 15301

Tel.: 237484988



OF:CAP.Care.001.01 Issue/Rev no.: 1/0 Issue Date: 30/09/2021 Rev Date:.../.... Page 2 of 2







Ext.:1470