GlaxoSmithKline
Scientific Office

جلاكسو سميث كلاين
المكتب العلمي

ترخيص رقم 00047 – 59 - 32 - 101
رقم العضوية 68583

Date: 14th April 2012

ZOFRAN® (ONDANSETRON) USE AND THE RISK OF ABNORMAL CHANGES IN THE ELECTRICAL ACTIVITY OF THE HEART

DEAR HEALTHCARE PROFESSIONAL

GlaxoSmithKline would like to inform you about important safety information concerning the use of Zofran® (ondansetron) and increased risk of developing abnormal changes in the electrical activity of the heart. These changes include QT prolongation which can lead to abnormal and potentially fatal heart rhythm (including Torsade de Pointes).

ZOFRAN® (ondansetron) is a 5-HT3 antagonist licensed for use in for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy (CINV) and for the prevention and treatment of post-operative nausea and vomiting (PONV).

The Saudi Food and Drug Authority (SFDA) has requested distribution of this safety advisory to make prescribers aware that GSK has updated the prescribing information for ZOFRAN® (Ondansetron) to include information about QT interval prolongation and case reports of Torsade de Pointes.

GSK is currently conducting a thorough QTc study to characterize the arrhythmogenic potential of ondansetron with results expected before the end of 2012. These results will be shared with regulatory agencies and product labeling will be updated as necessary.

CONSIDERATIONS FOR HEALTHCARE PROFESSIONALS:

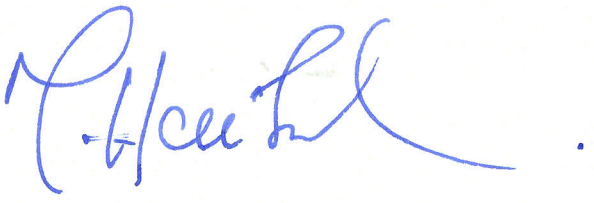
- QT interval prolongation and cases of Torsade de Pointes have been reported in patients using ondansetron.
- You are advised to assess your patients for risk factors for QT interval prolongation or Torsade de Pointes before prescribing ondansetron.
- Avoid ondansetron in patients with congenital long QT syndrome.
- ECG monitoring is recommended in patients with electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, bradyarrhythmias, or patients taking other medicinal products that lead to QT prolongation.
- Patients should be advised to contact health care professionals if they experience signs and symptoms of the abnormal heart rate or rhythm while taking ondansetron.
- Report adverse events involving ondansetron to the National Pharmacovigilance and Drug Safety Center at SFDA using the information in the "Call for Reporting" section.

ص . ب 309 الرياض 11411 المملكة العربية السعودية ، هاتف 4642826 ، فاكس 4653185
P.O. Box 309 Riyadh 11411 Saudi Arabia Tel.: (01) 464 2826 Fax: (01) 465 3185

CALL FOR REPORTING:

GlaxoSmithKline will continue to monitor the safety of Zofran® and notify SFDA of any serious adverse events for evaluation. You can assist us in monitoring the safety of Zofran® by reporting adverse reactions to us fax +966 2653 6660 or by email to GlaxoSmithKline safety email: faisal.m.shujrah@gsk.com
Or to the National Pharmacovigilance and Drug safety center at fax: +966-1-2057662 or by Email to: npc.drug@sfda.gov.sa
If you have any questions about the new information, please contact GSK Medical Information Department at GlaxoSmithKline Saudi Arabia Fax: +966 2653 6660 or email: mohammedatef.a.soliman@gsk.com

Best regards,



Mohamed Hany Soliman
Medical Director
GlaxoSmithKline
Saudi Arabia