Roche

From: Dr.Moataz Elwarwary
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16 November 2011

Subject. Important Changes in the Kytril® (granisetron hydrochloride) Prescribing Information-QTc Prolongation has been reported in Patients treated with Kytril®

Dear Healthcare professional:

Roche would like to inform you that based on a recently completed pediatric study, and on post-marketing data from the Roche worldwide adverse event reporting system, QTc prolongation has been reported in patients treated with Kytril®. The new QTc prolongation safety information has been added to the WARNINGS/PRECAUTIONS, DRUG INTERACTIONS, ADVERSE PRACTIONS, and POSTMARKETING experience sections of the Kytril® prescribing information. This new important safety information in Kytril® prescribing information includes revisions to product labeling regarding QTc prolongation as the following:-

WARNINGS AND PRECAUTIONS:

An adequate QT assessment has not been conducted, but QTc prolongation has been reported with Kytril®Therefore Kytril® should be used with caution in patients with pre-existing arrhythmias or cardiac conduction disorders, as this might lead to clinical consequences. Patients with cardiac disease, on cardio-toxic chemotherapy, with concomitant electrolyte abnormalities and/or on concomitant medications that prolong the QT interval are particularly at risk.

DRUG INTERACTIONS:

QTc prolongation has been reported with Kytril®. Use of Kytril®in patients concurrently treated with drugs known to prolong the QT interval and/or is arrhythmogenic may result in clinical consequences.

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ADVERSE REACTIONS:

QTc prolongation has been reported with Kytril® [see warning and precautions and Drug Interactions section].

POSTMARKETING EXPEREIENCE:

QTc prolongation has been reported with Kytril® [see warning and Drug Interactions section].
Roche will continue monitoring the safety for Kytril® and notify Saudi Food and Drug Authority (SFDA) of any serious adverse events for evaluation.
You can assist us in monitoring the safety of Kytril® by reporting adverse reactions to us at
Fax: +966 2 284 7198 OR +966 2 2847198 Ext 131 Or by e-mail to Roche Safety mail :
jeddah.drug_safety@roche.com
Or to the Saudi Food And Drug Authority – National Pharmacovigilance and Drug Safety Center at:
Fax: +966 1 2057662 or by e-mail to: •NPC.Drug@sfda.gov.sa

Important information about Kytril® (granisetron hydrochloride)

INDICATIONS:

Kytril® Injection is a serotonin-3 (5-HT3) receptor antagonist indicated for:

- Prevention of nausea and/or vomiting associated with initial and repeat courses of emetogenic cancer Therapy, including high-dose cisplatin
- Prevention and treatment of postoperative nausea and vomiting in adults

As with other antiemetic's, routine prophylaxis is not recommended in patients in whom there is little Expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or Vomiting must be avoided during the postoperative period, Kytril® Injection is recommended even where The incidence of postoperative Nausea and/or vomiting is low.

KYTRIL tablets and oral solutions are indicated for:

- Nausea and vomiting associated with initial and repeated courses of emetogenic cancer therapy including high-dose cisplatin.
- Nausea and vomiting associated with radiation including total body irradiation and fractionated abdominal radiations

CONTRAINDICATIONS:

Kytril® Injection is contraindicated in patients with known hypersensitivity (eg. anaphylaxis, shortness of

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breath, hypotension, and urticaria) to the drug or to any of its components.

IMPORTANT SAFETY INFORMATION:

QTc prolongation has been reported with Kytril®. Therefore, Kytril® should be used with caution in patients with pre-existing arrhythmias or cardiac conduction disorders, as this might lead to clinical consequences. Patients with cardiac disease, on cardiac toxic chemotherapy, with concomitant electrolyte abnormalities and/or on concomitant medications that prolong the QT interval are particularity at risk.
The most frequently reported clinical adverse events occurring in patients receiving Kytril® were headache, constipation, asthenia, diarrhea, abdominal pain ± dyspepsia ± pain*, anemia*, fever* and elevated hepatic enzymes*. The use of Kytril® in patients following abdominal surgery or in patients with chemotherapy induced nausea and vomiting may mask progressive ileus and /or gastric distention.
Please see the Kytril® complete prescribing information, which includes additional information for warning, precautions, dosage and administration. If you have any questions or required additional information regarding the use of Kytril® , please contact Roche Saudi Arabia team at 00966-2-28 47 190 Ext 105 & 221 from 9:00 AM to 5: 00 PM Saturday through Wednesday.

± associated with Kytril® tablet only.
* associated with Kytril® injection for postoperative nausea and vomiting only.

Sincerely

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Hazem Dajani
Safety Responsible

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