

הודעה על החמרה (מידע בטיחות)

(מעודכן 05.2013)

תאריך Nov 2017

שם תכשיר באנגלית **NOXAFIL 100 MG GASTRO-RESISTANT TABLETS**

מספר הרישום **156 42 34550 00**

שם בעל הרישום **Merck Sharp & Dohme (Israel – 1996) Company Ltd.**

טופס זה מיועד לפרוט ההחמרות בלבד !

בעלון לרופא

החמרות המבוקשות		
פרק בעלון	טקסט נוכחי	טקסט חדש
4.4 Special warnings and precautions for use		<p>4.4 Special warnings and precautions for use</p> <p><u>Drug Interactions</u></p> <p>...</p> <p>Vincristine Toxicity</p> <p>Concomitant administration of azole antifungals, including posaconazole, with vincristine has been associated with neurotoxicity and other serious adverse reactions, including seizures, peripheral neuropathy, syndrome of inappropriate antidiuretic hormone secretion, and paralytic ileus. Reserve azole antifungals, including posaconazole, for patients receiving a vinca alkaloid, including vincristine, who have no alternative antifungal treatment options (see section 4.5).</p>
4.5 Interaction with other medicinal products and other forms of interaction		<p>4.5 Interaction with other medicinal products and other forms of interaction</p> <p>....</p> <p><i>Vinca alkaloids</i></p> <p>Most of the vinca alkaloids (e.g., vincristine and vinblastine) are substrates of CYP3A4.</p> <p>Concomitant administration of azole antifungals, including posaconazole, with vincristine has been associated with serious adverse reactions (see section 4.4).</p> <p>Posaconazole may increase the plasma concentrations of vinca alkaloids which may lead to neurotoxicity and other serious adverse reactions. Therefore, reserve azole antifungals, including posaconazole, for patients receiving a vinca alkaloid, including vincristine, who have no alternative antifungal treatment options.</p>
	<p>Vinca alkaloids</p> <p>Posaconazole may increase the plasma concentration of vinca alkaloids (e.g. vincristine and vinblastine), which may lead to neurotoxicity. Therefore, concomitant use of posaconazole and vinca alkaloids should be avoided unless the benefit to the patient outweighs the risk. If co-administered, then it is recommended that dose adjustment of vinca alkaloids be considered.</p>	

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p>....</p> <p>• הינך נוטל וינקריסטין, וינבלסטין ו"אלקלואידים מסוג וינקה" אחרים (תרופות המשמשות לטיפול בסרטן).</p>		<p>2.2 אזהרות מיוחדות בנוגע לשימוש בנוקספיל</p>
