

הודעה על החמרה (מידע בטיחות)

(מעודכן 05.2013)

תאריך 24 Nov 2017

שם תכשיר באנגלית NOXAFIL SUSPENSION

מספר הרישום 138 37 31627 01, 138 37 31627 00

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

טופס זה מיועד לפרוט ההחמרות בלבד !

בעלון לרופא

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
<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>		<p>4.4 Special warnings and precautions for use</p>
<p><i>Vinca alkaloids</i></p> <p>Most of the vinca alkaloids (e.g., vincristine and vinblastine) are substrates of CYP3A4. Concomitant administration of azole antifungals, including posaconazole, with vincristine has been associated with serious adverse reactions (see section 4.4). 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><i>Vinca alkaloids</i></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>	<p>4.5 Interaction with other medicinal products and other forms of interaction</p>

ההחמרות המבוקשות		
פרק בעלון	טקסט נוכחי	טקסט חדש
2.2 אזהרות מיוחדות בנוגע לשימוש בנוקספיל		<p>.....</p> <ul style="list-style-type: none"> הינך נוטל וינקריסטין, וינבלסטין ו"אלקלואידים מסוג וינקה" אחרים (תרופות המשמשות לטיפול בסרטן).
