

הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05/2013)

תאריך _____ January 20, 2015

שם תכשיר באנגלית ומספר הרישום

VINCRIStINE Solution for Injection

115 51 22790 05

שם בעל הרישום Salomon, Levin & Elstein Ltd. POBox 3696, Petach-Tikva 49133

טופס זה מיועד לפרוט החמרות בלבד !

החמרות המבוקשות

פרק בעלון	טקסט נוכחי	טקסט חדש
Indication		
contraindications	in patients who are hypersensitive to vincristine sulphate or to one of the excipients;	in patients who are hypersensitive to active substance or to any excipient listed in section 6.1 vincristine sulphate or to one of the excipients;
Posology, dosage & administration		
Special Warnings and Special Precautions for Use	VINCRIStINE FOR INTRAVENOUS USE ONLY, FATAL IF GIVEN BY OTHER ROUTES' Intrathecal administration of vincristine results in fatal neurotoxicity.	'VINCRIStINE FOR INTRAVENOUS USE ONLY, FATAL IF GIVEN BY OTHER ROUTES' Intrathecal administration of vincristine results in fatal neurotoxicity.
Interaction with Other Medicaments and Other Forms of Interaction		
pregnancy and Fertility, Lactation		
Adverse events		<p><i>Nervous system disorders</i> Not known: Leukoencephalopathy</p> <p>Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form (http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il).</p>

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