

הודעה על החמרה (מידע בטיחות) בעלון לרופא
 (מעודכן 05.2013)

תאריך: 10/10/2016

שם תכשיר באנגלית ומספר רישום: Halaven 148-18-33511

שם בעל הרישום: Neopharm Scientific Ltd.

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
<p><u>Summary of safety profile</u></p> <p>The most commonly reported adverse reactions related to HALAVEN, are bone marrow suppression manifested as neutropenia, leucopenia, anaemia, thrombocytopenia with associated infections. New onset or worsening of pre-existing peripheral neuropathy has also been reported. Gastrointestinal toxicities, manifested as anorexia, nausea, vomiting, diarrhoea, constipation, and stomatitis are among reported undesirable effects. Other undesirable effects include fatigue, alopecia, increased liver enzymes, sepsis and musculoskeletal pain syndrome.</p> <p><u>Tabulated list of adverse reactions</u></p> <p>Unless otherwise noted, the table shows the incidence rates of adverse reactions observed in breast cancer and soft tissue sarcoma patients who received the recommended dose in Phase 2 and Phase 3 studies. [...]</p>	<p><u>Summary of safety profile</u></p> <p>The most commonly reported adverse reactions related to HALAVEN, are bone marrow suppression manifested as neutropenia, leucopenia, anaemia, thrombocytopenia with associated infections. New onset or worsening of pre-existing peripheral neuropathy has also been reported. Gastrointestinal toxicities, manifested as anorexia, nausea, vomiting, diarrhoea, constipation, and stomatitis are among reported undesirable effects. Other undesirable effects include fatigue, alopecia, increased liver enzymes, sepsis and musculoskeletal pain syndrome.</p> <p><u>Tabulated list of adverse reactions</u></p> <p>Unless otherwise noted, the table shows the incidence rates of adverse reactions observed in breast cancer and soft tissue sarcoma patients who received the recommended dose in Phase 2 and Phase 3 studies. [...]</p>	<p>4.8 Undesirable effects</p>

System Organ Class	Adverse Reactions – all Grades				System Organ Class	Adverse Reactions – all Grades			
	Very Common (Frequency %)	Common (Frequency %)	Uncommon (Frequency %)	Rare or not known		Very Common (Frequency %)	Common (Frequency %)	Uncommon (Frequency %)	Rare
Skin and subcutaneous tissue disorders	Alopecia	Rash (4.9%) (G3/4: 0.1%) Pruritus (3.9%) (G3/4: 0.1%) ^d Nail disorder Night sweats Dry skin Erythema Hyperhidrosis Palmar plantar erythrodysesthesia (1.0%) (G3/4: 0.1%) ^d	Angioedema	^a Stevens- Johnson syndrome/ Toxic epidermal necrolysis ^b	Skin and subcutaneous tissue disorders	Alopecia	Rash (4.9%) (G3/4: 0.1%) Pruritus (3.9%) (G3/4: 0.1%) ^d Nail disorder Night sweats Dry skin Erythema Hyperhidrosis Palmar plantar erythrodysesthesia (1.0%) (G3/4: 0.1%) ^d	Angioedema	
[...]					[...]				

