# הודעה על החמרה ( מידע בטיחות) בעלון לרופא

# (מעודכן 05.2013)

**תאריך 02/2014**

**שם תכשיר באנגלית ומספר הרישום HYCAMTIN: 104-89-28936**

**שם בעל הרישום GlaxoSmithKline (ISRAEL) Ltd :**

טופס זה מיועד לפרוט ההחמרות בלבד !

בעלון לרופא

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| **ההחמרות המבוקשות** | | |
| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **Undesirable effects** | **Blood and lymphatic system disorders**  Very Common: Anaemia, febrile neutropenia, leucopenia, neutropenia, thrombocytopenia  Not known: Severe bleeding (associated with thrombocytopenia) | **Blood and lymphatic system disorders**  Very common: febrile neutropenia, neutropenia (see Gastrointestinal disorders), thrombocytopenia, anaemia, leucopenia  Common: pancytopenia  Not known: severe bleeding (associated with thrombocytopenia) |
| **Skin and subcutaneous disorders**  Very Common: Alopecia | **Skin and subcutaneous tissue disorders**  Very common: alopecia  Common: pruritus |
| **Infections and infestations**  Common: Infection, sepsis (see Warnings and Precautions) | **Infections and infestations**  Very common: infection  Common: sepsis |
| **Immune system disorders**  Common: Hypersensitivity, including rash | **Immune system disorders**  Common: hypersensitivity reaction including rash  Rare: anaphylactic reaction, angioedema, urticaria |
| **-** | The incidence of adverse events listed above have the potential to occur with a higher frequency in patients who have a poor performance status (see section 4.4). |
| Overdosage | Symptoms and Signs  The primary complications of overdosage are anticipated to be bone marrow suppression and stomatitis.  Treatment  There is no known antidote for topotecan overdosage. | Overdoses (up to 10-fold of the prescribed dose) occurred in patients treated with intravenous topotecan. The primary complication of overdosage is bone marrow suppression. The observed signs and symptoms of overdose are consistent with the known adverse reactions associated with HYCAMTIN for intravenous use. In addition, elevated hepatic enzymes and mucositis have been reported following overdose. One patient received a single dose of 40 mg/m2 of intravenous topotecan and developed gastrointestinal toxicity, skin toxicity, and myelosuppresion leading to septic shock. Another patient received a single dose of 35 mg/m2 and experienced severe, reversible neutropenia.  There is no known antidote for overdosage with HYCAMTIN. If an overdose is suspected, monitor the patient for bone marrow suppression and institute supportive-care measures (such as prophylactic G-CSF and antibiotic therapy) as appropriate. |

**מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.** שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע ירוק.