הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 3102.50)

תאריך _____30.11.2014_____

שם תכשיר באנגלית Evoltra

מספר רישום 140 11 31946

שם בעל הרישום __סאנופי-אוונטיס ישראל _____

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
מידע שהתווסף ומהווה החמרה מסומן בצהוב , מידע מלא של סעיף זה ניתן למצוא בעלון המלא): *Paediatric population* The recommended dose **in monotherapy** is 52 mg/m^2 of body surface area administered by intravenous infusion over 2 hours daily for 5 consecutive days. Body surface area must be calculated using the actual height and weight of the patient before the start of each cycle. Treatment cycles should be repeated every 2 to 6 weeks (from the starting day of the previous cycle) following recovery of normal haematopoiesis (i.e. ANC $\geq 0.75 \times 10^9$/l) and return to baseline organ function. A 25% dose reduction may be warranted in patients experiencing significant toxicities (see below). There is currently limited experience of patients receiving more than 3 treatment cycles (see section 4.4).		**Posology and method of administration**
מידע שהתווסף ומהווה החמרה מסומן בצהוב , מידע מלא של סעיף זה ניתן למצוא בעלון המלא): Occurrences of enterocolitis, including neutropaenic colitis, *C. difficile* colitisand caecitis, have been reported during treatment with clofarabine. This has occurred more frequently within 30 days of treatment, and in the setting of combination chemotherapy. Enterocolitis may lead to necrosis, perforation or sepsis complications and may be associated with fatal outcome (see section 4.8). Patients should be monitored for signs and symptoms of enterocolitis. Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), including fatal cases, have been reported (see section 4.8). Clofarabine must be discontinued for exfoliative or bullous rash, or if SJS or TEN is suspected.		**Special warnings and precautions for use**

…….. **It was observed that the frequency and severity of adverse reactions, in particular infection, myelosuppression (neutropenia) and hepatotoxicity, are increased when clofarabine is used in combination. In this regard, patients should be closely monitored when clofarabine is used in combined regimens.**		
מידע שהתווסף ומהווה החמרה מסומן בצהוב , מידע מלא של סעיף זה ניתן למצוא בעלון המלא): **Adverse reactions considered to be related to clofarabine reported at frequencies ≥ 1/100 (i.e. in > 1/115 patients) in clinical trials and post-marketing:** **…….** Metabolism and nutrition disorders: *Frequency not known:* hyponatremia …….. During the post-marketing period prolonged cytopaenias (thrombocytopaenia, anaemia, neutropaenia and leukopaenia) and bone marrow failure have been reported. Bleeding events have been observed in the setting of thrombocytopaenia. Hemorrhage, including cerebral, gastrointestinal and pulmonaryhemorrhage, has been reported and may be associated with a fatal outcome (see section 4.4). Vascular disorders: Sixty-four patients of 115 (55.7%) experienced at least one vascular disorders adverse event. Twenty-three patients out of 115 experienced a vascular disorder considered to be related to clofarabine, the most frequently reported being flushing (13 events; not serious) and hypotension (5 events; all ~~one~~ of which were considered to be serious; see section 4.4). However, the majority of these hypotensive events were reported in patients who had confounding severe infections.		**Undesirable effects**

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע ירוק, או אדום עם קו מחיקה (עבור מידע שאנו מבקשים להוריד).

הועבר בדואר אלקטרוני בתאריך.....30.11.2014.....

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