הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך 09/11/2015

שם תכשיר באנגלית ומספר הרישום Herceptin vials 440 mg [113-91-29676-00]

שם בעל הרישום רוש פרמצבטיקה (ישראל) בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות - עלון לרופא		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
[…] It is important to check the product labels to ensure that the correct formulation (intravenous or subcutaneous fixed dose) is being administered to the patient, as prescribed. Herceptin intravenous formulation is not intended for subcutaneous administration and should be administered via an intravenous infusion only. Switching treatment between Herceptin intravenous and Herceptin subcutaneous formulations and vice versa, using the three-weekly (q3w) dosing regimen, was investigated in study MO22982 (see section 4.8).		**Posology and method of administration**
In order to improve traceability of biological medicinal products, the trade name and the batch number of the administered product should be clearly recorded (or stated) in the patient file. […]	In order to improve traceability of biological medicinal products, the trade name of the administered product should be clearly recorded (or stated) in the patient file. […]	**Special warnings and precautions for use**
[…] Immunogenicity In the neoadjuvant-adjuvant EBC treatment setting, 8.1 % (24/296) of patients treated with Herceptin intravenous developed antibodies against trastuzumab (regardless of antibody presence at baseline). Neutralizing anti-trastuzumab antibodies were detected in post-baseline samples in 2 of 24 Herceptin intravenous patients. The clinical relevance of these antibodies is not known; nevertheless the pharmacokinetics, efficacy (determined by pathological Complete Response [pCR]) and safety determined by occurrence of administration related reactions (ARRs) of Herceptin intravenous did not appear to be adversely affected by these antibodies. There are no immunogenicity data	[…]	**Undesirable effects**

available for Herceptin in gastric cancer. Switching treatment between Herceptin intravenous and Herceptin subcutaneous formulation and vice versa Study MO22982 investigated switching between the Herceptin intravenous and Herceptin subcutaneous formulation with a primary objective to evaluate patient preference for either intravenous or the subcutaneous route of trastuzumab administration. In this trial, 2 cohorts (one using subcutaneous formulation in vial and one using subcutaneous formulation in administration system) were investigated using a 2-arm , cross-over design with 488 patients being randomized to one of two different three-weekly Herceptin treatment sequences (IV [Cycles 1-4]→ SC [Cycles 5-8], or SC [Cycles 1-4]→ IV [Cycles 5-8]). Patients were either naïve to Herceptin IV treatment (20.3%) or pre-exposed to Herceptin IV (79.7%). For the sequence IV→SC (SC vial and SC formulation in administration system cohorts combined), adverse event rates (all grades) were described pre-switching (Cycles 1-4) and post-switching (Cycles 5-8) as 53.8% vs. 56.4%, respectively; for the sequence SC→IV (SC vial and SC formulation in administration system cohorts combined), adverse event rates (all grades) were described pre- and post-switching as 65.4% vs. 48.7%, respectively. Pre-switching rates (Cycles 1-4) for serious adverse events, grade 3 adverse events and treatment discontinuations due to adverse events were low (<5%) and similar to post-switching rates (Cycles 5-8). No grade 4 or grade 5 adverse events were reported.		