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

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שם תכשיר באנגלית ומספר הרישום Halaven (148-18-33511-00/01/02)

שם בעל הרישום Neopharm Scientific Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**

{..} *Patients with renal impairment* Some patients with moderately or severely impaired renal function (creatinine clearance <50 ml/min) may have increased eribulin exposure and may need a reduction of the dose.. For all patients with renal impairment, caution and close safety monitoring is advised. (See section 5.2) *{..}*	*{..}* *Patients with renal impairment* Patients with severely impaired renal function (creatinine clearance <40 ml/min) may need a reduction of the dose. The optimal dose for this patient groups remains to be established. Caution and close safety monitoring as advised. No specific dose adjustments are recommended for patients with mild to moderate renal impairment but close safety monitoring is advised. (See section 5.2) *{..}*	**4.2 Posology and method of administration**
[..] Renal impairment Increased eribulin exposure was seen in some patients with moderately or severely impaired renal function, with high between-subject variability. The pharmacokinetics of eribulin were evaluated in a Phase 1 study in patients with normal renal function (Creatinine clearance: ≥ 80 ml/min; n=6), moderate (30-50 ml/min; n=7) or severe (15-<30 ml/min; n=6) renal impairment. Creatinine clearance was estimated with the Cockcroft-Gault formula. A 1.5-fold (90% CI: 0.9-2.5) higher dose-normalised $AUC_{(0\text{-}inf)}$ was observed in patients with moderate and severe renal impairment. See section 4.2 for treatment recommendations. [..]	*{..}* Renal impairment Data in patients with different degrees of impaired renal function showed that the exposure of eribulin in patients with mild to moderate renal impairment (creatinine clearance ≥ 40 to 80 ml/min) was increased in some patients, as compared to patients with normal renal function. The mean exposure in patients with severe impairment was increased by 75% (creatinine clearance < 40 ml/min, n=4). See section 4.2 for treatment recommendations. *{..}*	**5.2 Pharmacokinetic properties**
HALAVEN is a cytotoxic anticancer medicinal product and, as with other toxic compounds, caution should be exercised in its handling. The use of gloves, goggles, and protective clothing is recommended. If the skin comes into contact with the solution it should be washed immediately and thoroughly with soap and water. If it contacts mucous membranes, the membranes should be flushed thoroughly with water. HALAVEN should only be prepared and administered by personnel appropriately trained in handling of cytotoxic agents. Pregnant staff should not handle HALAVEN. Using aseptic technique HALAVEN can be diluted up to 100 ml with sodium chloride 9 mg/ml (0.9%) solution for injection. Following administration, it is recommended that the intravenous line be flushed with sodium chloride 9 mg/ml (0.9%) solution for injection to ensure administration of the complete dose. It must not be mixed with other medicinal products and should not be diluted in glucose 5% infusion solution. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.		**6.6 Special precautions for disposal and other handling**