הודעה על החמרה (מידע בטיחות)

טקסט שחור : טקסט מעלון מאושר בנובמבר 2010
קו תחתי – תוספת טקסט לעלון המאושר
~~קו חוצה~~ – מחיקת טקסט מהעלון המאושר
טקסט מודגש בצהוב - טקסט המהווה החמרה

תאריך:

שם התכשיר באנגלית: Aclasta

מספר רישום: [31323]

שם בעל הרישום : נוברטיס פארמה סרויסס איי ג'י

השינויים בעלון מסומנים ברקע צהוב

עלון לרופא

פרטים על השינוי/ים המבוקש/ים		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
Warnings and precautions		**Renal impairment** The use of Aclasta in patients with severe renal impairment (creatinine clearance <35 mL/min) is contraindicated due to an increased risk of renal failure in this population. … **Atypical fractures of the femur** Atypical subtrochanteric and diaphyseal femoral fractures have been reported in association with bisphosphonate therapy, primarily in patients receiving long-term treatment for osteoporosis. These transverse or short oblique fractures can occur anywhere along the femur from just below the lesser trochanter to just above the supracondylar flare. These fractures occur after minimal or no trauma and some patients experience thigh or groin pain weeks to months before presenting with a completed femoral fracture. Fractures are often bilateral; therefore the contralateral femur should be examined in bisphosphonate-treated patients who have sustained a femoral shaft fracture. Poor healing of these fractures has also been reported. Discontinuation of bisphosphonate therapy in patients suspected to have an atypical femur

fracture should be considered pending evaluation of the patient, based on an individual benefit risk assessment. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with bisphosphonates. During bisphosphonate treatment, including Aclasta, patients should be advised to report any thigh, hip or groin pain and any patient presenting with such symptoms should be evaluated for possible femur fracture.		
Severe renal impairment with creatinine clearance <35 mL/min (see section 6 Warnings and precautions).		**Contraindications**
		Adverse drug reactions
		Interactions
Dosage and administration … **Special populations** **Patients with renal impairment:** The use of Aclasta in patients with creatinine clearance < 35 mL~~l~~/min is contraindicated ~~not recommended due to limited clinical safety data in such patients~~ (see section 5 contraindications and 6 Warnings and precautions). No dose adjustment is necessary in patients with creatinine clearance ≥ 35 mL/min.	**Dosage and administration** … **Special populations** **Patients with renal impairment:** The use of Aclasta in patients with creatinine clearance < 35 ml/min is not recommended due to limited clinical safety data in such patients (see section 6 Warnings and precautions). No dose adjustment is necessary in patients with creatinine clearance ≥ 35 mL/min.	**Others**