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

תאריך: 12.4.2016

שם תכשיר באנגלית ומספר הרישום: ACLASTA ® [135-99-31323]

שם בעל הרישום: נוברטיס ישראל בע"מ

טופס זה מיועד לפירוט ההחמרות בלבד!

טקסט שחור – טקסט מאושר
טקסט עם קו תחתי – הוספת טקסט לעלון המאושר
~~טקסט עם קו חוצה~~ – מחיקת טקסט מהעלון המאושר
טקסט המסומן בצהוב – החמרה

ההחמרות המבוקשות		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
4.2 Posology and method of administration	…	Posology … *Osteoporosis* … The optimal duration of bisphosphonate treatment for osteoporosis has not been established. The need for continued treatment should be re-evaluated periodically based on the benefits and potential risks of Aclasta on an individual patient basis, particularly after 5 or more years of use. …

Hypocalcaemia Patients should be informed about symptoms of hypocalcaemia and receive adequate clinical monitoring during the period of risk. Measurement of serum calcium before infusion of Aclasta is recommended for patients with Paget´s disease. ~~Physicians should consider clinical monitoring for patients at risk.~~ …	**6. Warnings and precautions** … Patients should be informed about symptoms of hypocalcaemia. Physicians should consider clinical monitoring for patients at risk. …	**4.4 Special warnings and precautions for use**
Osteonecrosis of the Jaw (ONJ) ONJ has been reported in the post-marketing setting in patients receiving Aclasta (zoledronic acid) for osteoporosis (see section 4.8). The start of treatment or of a new course of treatment should be delayed in patients with unhealed open soft tissue lesions in the mouth. A dental examination with preventive dentistry and an individual benefit-risk assessment is recommended prior to treatment with Aclasta in patients with concomitant risk factors. The following should be considered when evaluating a patient's risk of developing ONJ: - Potency of the medicinal product that inhibits bone resorption (higher risk for highly potent compounds), route of administration (higher risk for parenteral administration) and cumulative dose of bone resorption therapy. - Cancer, co-morbid conditions (e.g. anaemia, coagulopathies, infection), smoking. - Concomitant therapies: corticosteroids, chemotherapy, angiogenesis inhibitors, radiotherapy to head and neck. - Poor oral hygiene, periodontal disease, poorly fitting dentures, history of dental disease, invasive dental procedures, e.g. tooth extractions. All patients should be encouraged to maintain good oral hygiene, undergo routine dental check-ups, and immediately report any oral symptoms such as dental mobility, pain or swelling, non-healing of	**Osteonecrosis of the Jaw** Osteonecrosis of the jaw (ONJ): Osteonecrosis of the jaw has been reported predominantly in cancer patients treated with bisphosphonates, including zoledronic acid. Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. Many had signs of local infection including osteomyelitis. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g. cancer, chemotherapy, anti-angiogenic drugs, corticosteroids, poor oral hygiene). While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop osteonecrosis of the jaw while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of osteonecrosis of the jaw. The clinical judgement of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.	**4.4 Special warnings and precautions for use**

sores or discharge during treatment with zoledronic acid. While on treatment, invasive dental procedures should be performed with caution and avoided in close proximity to zoledronic acid treatment. The management plan for patients who develop ONJ should be set up in close collaboration between the treating physician and a dentist or oral surgeon with expertise in ONJ. Temporary interruption of zoledronic acid treatment should be considered until the condition resolves and contributing risk factors are mitigated where possible. ~~Osteonecrosis of the jaw (ONJ): Osteonecrosis of the jaw has been reported predominantly in cancer patients treated with bisphosphonates, including zoledronic acid. Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. Many had signs of local infection including osteomyelitis. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g. cancer, chemotherapy, anti-angiogenic drugs, corticosteroids, poor oral hygiene). While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop osteonecrosis of the jaw while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of osteonecrosis of the jaw. The clinical judgement of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.~~		

Osteonecrosis of other bones Cases of osteonecrosis of other bones (including femur, hip, knee and humerus) have also been reported; however, causality has not been determined in the population treated with Aclasta.	…	**4.4 Special warnings and precautions for use**
Osteonecrosis of the external auditory canal Osteonecrosis of the external auditory canal has been reported with bisphosphonates, mainly in association with long-term therapy. Possible risk factors for osteonecrosis of the external auditory canal include steroid use and chemotherapy and/or local risk factors such as infection or trauma. The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving bisphosphonates who present with ear symptoms including chronic ear infections.	…	**4.4 Special warnings and precautions for use**
Treatment of postmenopausal osteoporosis, osteoporosis in men, prevention of clinical fractures after low trauma hip fracture, treatment and prevention of glucocorticoid-induced osteoporosis and Paget's disease of the bone: … **Class adverse events** Rare — Atypical subtrochanteric and diaphyseal femoral fractures† (bisphosphonate class adverse reaction) Very Rare — Osteonecrosis of the external auditory canal (bisphosphonate class adverse reaction)	…	**4.8 Undesirable effects**