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Javna agencija Republike Slovenije
za zdravila in medicinske pripomočke

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Vsem imetnikom dovoljenj za promet z zdravili, ki vsebujejo alendronsko kislino

ZAHTEVA ZA PREDLOŽITEV SPREMEMBE TIPA II – dopolnitev povzetka glavnih značilnosti zdravila (SmPC) in navodila za uporabo (PIL) za celotno skupino zdravil, ki vsebujejo alendronsko kislino, v povezavi s stresnimi zlomi proksimalnega dela diafize stegenice

Spoštovani,

Delovna skupina za farmakovigilanco (PhVWP) je ocenila podatke v zvezi s tveganjem stresnih zlomov proksimalnega dela diafize stegenice v povezavi z zdravljenjem z alendronsko kislino in aprila 2009 izdala priporočilo za dopolnitev povzetka glavnih značilnosti zdravil in navodil za uporabo zadevnih zdravil z novimi informacijami.


Imetnike dovoljenj za promet z zadevnimi zdravili prosimo, da Javni agenciji RS za zdravila in medicinske pripomočke v skladu s Pravilnikom o dovoljenju za promet z zdravilom za uporabo v humani medicini (Uradni list RS, št. 59/2006) predložijo spremembo tipa II čim prej, oz. najkasneje v 30 dneh po prejemu obvestila. Dodatne informacije in podpora dokumentacija v vlogi niso potrebne. Ta dopis je objavljen na spletni strani JAZMP www.jazmp.si.

V nadaljevanju vam podajamo odobreno originalno besedilo spremembe.

Besedilo je objavljeno tudi na spletni strani Vodij agencij za zdravila <http://www.hma.eu>.

S spoštovanjem,




dr. Martina Cvelbar, mag.farm., spec.
Direktorica

SPC

Section 4.4 Special warnings and precautions for use

Stress fractures (also known as insufficiency fractures) of the proximal femoral shaft have been reported in patients treated long-term with alendronic acid (time to onset in the majority of cases ranged from 18 months to 10 years). The fractures occurred after minimal or no trauma and some patients experienced thigh pain, often associated with imaging features of stress fractures, weeks to months before presenting with a completed femoral fracture.

Fractures were 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 was also reported. Discontinuation of bisphosphonate therapy in patients with stress fracture is advisable pending evaluation of the patient, based on an individual benefit risk assessment.

Section 4.8 Undesirable effects

Stress fractures of the proximal femoral shaft (see section 4.4).

PIL

Section 4 Possible side effects

Fracture of the thigh bone in patients on long-term treatment with alendronic acid. Thigh pain, weakness or discomfort may be an early indication of a possible fracture of the thigh bone.