אוקטובר 2024

XGEVA (Denosumab 120 mg)
Solution for injection

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי. וי., בעלת הרישום, מבקשת להודיעך על עדכונים בעלון לרופא של התכשיר אקסג'יבה.
השינויים מפורטים להלן. קו תחתי מציין תוספת טקסט וקו חוצה מציין מחיקת טקסט.

ההתוויות המאושרות לתכשיר:
Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with multiple myeloma and in adults with bone metastases from solid tumors.

Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

העדכונים בעלון לרופא:

4.4 Special warnings and precautions for use

…
Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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Patients with Phenylketonuria (PKU)

The XGEVA 120 mg/1.7 mL solution in a single use vial does not contain phenylalanine. Patients with PKU should be administered XGEVA from the single use vial containing 120 mg in 1.7 mL solution.

4.8 Undesirable effects

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Study 7 was conducted to continue to follow patients with GCTB who were treated in study 6 for an additional 5 or more years. ONJ was reported in 6 patients (11.8%) of the 51 exposed patients with median total 42 doses of denosumab. Three of these cases of ONJ were medically confirmed.

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In the clinical trial program for GCTB, atypical femoral fractures have been reported commonly in patients treated with XGEVA. In study 6, incidence of confirmed AFF was 0.95% (5/526) in patients with giant cell tumor of bone. In the follow-up study 7, the incidence of confirmed AFF was 3.9% (2/51) of patients exposed to denosumab.

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In patients with giant cell tumor of bone, incidence of new malignancy, including malignancies involving the bone and outside the bone was 3.8% (20/526) in study 6. In the follow-up study 7, the incidence was 11.8% (6/51) of patients exposed to denosumab.

5.1 **Pharmacodynamic properties** was updated with clinical efficacy and safety information from studies 6 and 7 in adults and skeletally mature adolescents with giant cell tumor of bone.

6.6 **Special precautions for disposal and other handling**

- The carton contains a package leaflet with the full instructions for use and handling.
- Before administration, the XGEVA solution should be inspected visually. The solution may contain trace amounts of translucent to white proteinaceous particles. Do not inject the solution if it is cloudy, discolored or if it contains many particles or foreign particulate matter. ~~or discolored.~~

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו גם על-ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה.
שרות לקוחות: Medison-CS@medison.co.il טלפון: 5634*

בברכה,

אמג'ן אירופה בי. וי.