אפריל 2021

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.

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

4.2 Posology and method of administration
Pediatric population
The safety and efficacy of XGEVA have not been established in pediatric patients (age < 18) other than skeletally mature adolescents (aged 12-17 years) with giant cell tumor of bone.

XGEVA is not recommended in pediatric patients (age < 18) other than skeletally mature adolescents (aged 12–17 years) with giant cell tumor of bone (see section 4.4).

4.8 Undesirable effects
Description of selected adverse reactions
Osteonecrosis of the jaw (ONJ)
~~In two phase II single-arm clinical trials in patients with giant cell tumor of bone, ONJ occurred in 2.3% (12 of 523) of patients treated with XGEVA (median overall exposure of 20.3 months; range: 0 - 83.4). The patient-year adjusted incidence of ONJ was 0.2% during the first year of treatment and 1.7% in the second year. The median time to ONJ was 19.4 months (range: 11 - 40). Based on duration of exposure, there are insufficient data in giant cell tumor of bone patients to assess risk of ONJ beyond 2 years.~~

In a phase III trial in patients with non-metastatic prostate cancer (a patient population for which XGEVA is not indicated), with longer treatment exposure of up to 7 years, the patient-year adjusted incidence of confirmed ONJ was 1.1~~%~~ per 100 patient-years during the first year of treatment, 3.0~~%~~ in the second year, and 7.1~~%~~ ~~per year~~ thereafter.

In a long-term phase II open-label clinical trial in patients with giant cell tumo~~u~~r of bone (Study 6, see section 5.1), ONJ was confirmed in 6.8% of patients, including one adolescent (median number of 34 doses; range: 4 – 116). At the completion of the trial, median time on trial including safety follow-up phase was 60.9 months (range: 0 – 112.6). The patient-year adjusted incidence of confirmed ONJ was 1.5 per 100 patient-years overall (0.2 per 100 patient-years during the first year of treatment, 1.5 in the second year, 1.8 in the third year, 2.1 in the fourth year, 1.4 in the fifth year, and 2.2 thereafter). The median time to ONJ was 41 months (range: 11 - 96).

בהתאם לשינויים אלו, עודכנו גם הפרקים:
5.1 Pharmacodynamic properties **ו-** 5.2 Pharmacokinetic properties

העלונים לרופא ולצרכן המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם גם על-ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה.
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בברכה,
אילה רוהלד,
רוקחת ממונה