

Evenity (romosozumab)
Solution for injection

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי.וי, בעלת הרישום, מבקשת להודיעך על עדכונים בעלונים לרופא ולצרכן של התכשיר **Evenity**. בהודעה זו מפורטים השינויים המשמעותיים. קו תחתי מציין תוספת טקסט, קו חוצה מציין מחיקה.

ההתוויות המאושרות:

Treatment of Postmenopausal Women with Severe Osteoporosis at High Risk for Fracture

EVENTITY is indicated for the treatment of severe osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Limitations of Use

The anabolic effect of EVENTITY wanes after 12 monthly doses of therapy. Therefore, the duration of EVENTITY use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

שינויים בעלון לרופא:

2.3 Preparation and Administration Instructions

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Step 3: Inject EVENTITY

Pinch the skin around the injection site before injecting. Insert the needle into the pinched skin at or about a 45-degree angle. Insert needle and inject all the liquid subcutaneously. Do not administer into muscle or blood vessel. See Figure D.

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6. ADVERSE REACTIONS

6.2 Immunogenicity

~~As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies in the studies described below with the incidence of antibodies in other studies or to other romosozumab products may be misleading.~~

~~The immunogenicity of EVENTITY was evaluated using an immunoassay for the detection of anti-romosozumab antibodies. An *in vitro* biological assay was performed to detect neutralizing antibodies for those subjects whose sera tested positive for anti-romosozumab antibodies.~~

~~Among 5914 postmenopausal women treated with EVENTITY 210 mg monthly, 18.1% of subjects developed antibodies to romosozumab. Of the subjects who developed antibodies to romosozumab, 4.7% had antibodies that were classified as neutralizing. Development of antibodies to romosozumab was associated with lower serum romosozumab concentrations [see Clinical Pharmacology (12.3)]. Antibodies to~~

~~romosozumab were generally not associated with changes in the efficacy or safety of EVENITY.~~

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Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: <https://sideeffects.health.gov.il/> <https://reportsideffect.health.gov.il/drugs/home>

12. CLINICAL PHARMACOLOGY

12.3 PHARMACOKINETICS

Anti-Product Antibody Formation Affecting Pharmacokinetics

~~Development of anti-romosozumab antibodies was associated with reduced serum romosozumab concentrations. The presence of anti-romosozumab antibodies led to decreased mean romosozumab concentrations up to 22%. The presence of neutralizing antibodies led to decreased mean romosozumab concentrations up to 63% [see Adverse Reactions (6.2)].~~

12.4 Immunogenicity

The observed incidence of anti-drug antibodies (ADA) is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of ADA in the studies described below with the incidence of ADA in other studies, including those of EVENITY.

In studies of postmenopausal women treated with EVENITY 210 mg monthly for up to 1 year, the immunogenicity of EVENITY was evaluated for up to 2 years using an electrochemiluminescent bridging immunoassay. Among 5914 subjects treated with EVENITY, 18.1% developed antibodies to romosozumab. Of the subjects who developed antibodies to romosozumab, 4.7% had antibodies that were classified as neutralizing using an *in vitro* biological assay. Antibodies to romosozumab were generally not associated with changes in the efficacy or safety of EVENITY.

Anti-Product Antibody Formation Affecting Pharmacokinetics

Development of anti-romosozumab antibodies was associated with reduced serum romosozumab concentrations. The presence of anti-romosozumab antibodies led to decreased mean romosozumab concentrations up to 22%. The presence of neutralizing antibodies led to decreased mean romosozumab concentrations up to 63%. These anti-romosozumab antibody-associated pharmacokinetic changes were not identified to be clinically significant.

העדכונים בעלון לצרכן:

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4. תופעות לוואי

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<https://reportsideeffect.health.gov.il/drugs/home> <https://sideeffects.health.gov.il/>

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הוראות שימוש לזריקת איבניטי באמצעות מזרק מוכן לשימוש

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שלב 1: הכן

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- אל תסיר **עדיין** את המכסה האפור מהמזרקים המוכנים לשימוש עד שאתה מוכן להזריק.

שלב 2: התכונן

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- לאחר הסרת המכסה, יש לתת את הזריקה תוך 5 דקות. אל תשאיר את המכסה פתוח למשך יותר מ-5 דקות, שכן הדבר עלול לגרום להתייבשות התמיסה. אין צורך לזרז את ההזרקה – 5 דקות הינן מספיק זמן.

העלונים לרופא ולצרכן המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם גם על-ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה. שרות לקוחות: Medison-CS@medison.co.il טלפון: *5634

בברכה,
אמג'ן אירופה ב.י.וי.