פייזר פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

אוקטובר 2023

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלונים לרופא ולצרכן של **Enbrel powder and solvent** :

<u>המרכיב הפעיל:</u>

Etanercept 25 mg/vial

<u>צורת מינון:</u> Powder and solvent for solution for injection

<u>התוויה:</u>

<u>Rheumatoid arthritis</u>
Enbrel is indicated for the treatment of active rhematoid arthritis in adults when the response to disease-modifying antirheumatic drugs (DMARDs) including methotrexate (unless contraindicated) has been inadequate.

Enbrel can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone.
Reducing signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis.
Enbrel, alone or in combination with methotrexate, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.

<u>Juvenile idiopathic arthritis</u>
Treatment of polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.

Treatment of psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.

Treatment of enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy.

Enbrel has not been studied in children aged less than 2 years.

<u>Psoriatic arthritis</u>
Treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug therapy has been inadequate. *Enbrel has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease.*

<u>Axial spondyloarthritis</u>

Ankylosing spondylitis (AS)
Treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

Non-radiographic axial spondyloarthritis
Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs).

Plaque psoriasis
Treatment of adults patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Paediatric plaque psoriasis
Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

להלן העדכונים העיקריים בעלון לרופא:

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Allergic reactions
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The rubber tip cap (closure) of the diluent syringe contains latex (dry natural rubber) that may cause hypersensitivity reactions when handled by, or when Enbrel is administered to, persons with known or possible latex sensitivity.

4.6 FERTILITY, PREGNANCY AND LACTATION

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Breast-feeding
~~Etanercept has been reported to be excreted in human milk following subcutaneous administration.~~ In lactating rats following subcutaneous administration, etanercept was excreted in the milk and detected in the serum of pups. ~~Because immunoglobulins, in common with many medicinal products, can be excreted~~Limited information from the published literature indicates etanercept has been detected at low levels in human milk~~, a decision must be made whether to discontinue~~. Etanercept could be considered for use during breast-feeding ~~or to discontinue Enbrel therapy~~, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.
While systemic exposure in a breastfed infant is expected to be low because etanercept is largely degraded in the gastrointestinal tract, limited data regarding systemic exposure in the breastfed infant are available. Therefore, the administration of live vaccines (e.g., BCG) to a breastfed infant when the mother is receiving etanercept could be considered 16 weeks after stopping breast-feeding (or at an earlier timepoint if the infant etanercept serum levels are undetectable).

להלן העדכונים העיקריים בעלון לצרכן:

2. **לפני השימוש בתרופה**
אזהרות מיוחדות הנוגעות לשימוש בתרופה:
- **לטקס:** קצה הגומי של המזרק עשוי מלטקס (גומי טבעי יבש). יש לפנות לרופא לפני השימוש באנברל אם יעשה שימוש במזרק על ידי אדם או אם אנברל ינתן למטופל עם רגישות יתר (אלרגיה) ידועה או אפשרית ללטקס.

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השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.

העלונים המעודכנים נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
חיפוש במאגר התרופות | משרד הבריאות (www.gov.il)

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,
מרגריטה פולישצ'וק
רוקחת ממונה