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

יוני 2019

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא ובעלונים לצרכן של **Enbrel 25 mg pre filled syringe** ו- **Enbrel 50 mg solution for injection:**

<u>המרכיב הפעיל:</u>

ETANERCEPT 25 MG/DOSE; ETANERCPT 50 MG/DOSE

<u>Indicated for:</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>

<u>Ankylosing spondylitis(AS)</u>

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

<u>Non-radiographic axial spondyloarthritis</u>

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:

4.8 UNDESIRABLE EFFECTS

Tabulated list of adverse reactions
The following list of adverse reactions is based on experience from clinical trials in adults and on postmarketing experience.

Within the organ system classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

System Organ Class	Very Common ≥ 1/10	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1,000 to < 1/100	Rare ≥ 1/10,000 to < 1/1,000	Very Rare < 1/10,000	Frequency Not Known (Cannot be Estimated from Available Data)
Skin and subcutaneous tissue disorders		Pruritus, rash	Angioedema, psoriasis (including new onset or worsening and pustular, primarily palms and soles), urticaria, psoriasiform rash	Stevens-Johnson syndrome, cutaneous vasculitis (including hypersensitivity vasculitis), erythema multiforme, lichenoid reactions	Toxic epidermal necrolysis	

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להלן העדכונים העיקריים בעלון לצרכן:

4. תופעות לוואי

כמו בכל תרופה, השימוש באנברל™ עלול לגרום לתופעות לוואי בחלק מהמשתמשים. אל תיבהל למקרא רשימת תופעות הלוואי. יתכן ואתה/ הילד לא תסבול/יסבול מאף אחת מהן.

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תופעות לוואי נדירות (עשויות להופיע ב-עד 1 מכל 1,000 אנשים):

- ילפת (תגובה ליכנואידית) (פריחה אדמדמה-סגולה מגרדת ו\או קווים דמויי חוטים בצבע לבן-אפור על קרום ריריי).

אם הופיעה תופעת לוואי, אם אחת מתופעות הלוואי מחמירה, או כאשר אתה סובל מתופעת לוואי שלא צוינה בעלון, עליך להתייעץ עם הרופא.

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. העלונים המעודכנים זמינים באתר משרד הבריאות.

https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h

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