

2021 נובמבר

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

חברת נוברטיס ישראל בע"מ מבקשת להודיעכם על עדכונים בעלון לרופא ובעלונים לצרכן עבור:

Erelzi® 25

etanercept 25 mg / 0.5 ml

Solution for injection in pre-filled syringe

Erelzi® 50

etanercept 50 mg / 1 ml

Solution for injection in pre-filled syringe
Solution for injection in pre-filled pen

ההתוויות המאושרות לתכשירים:

Rheumatoid arthritis

Erelzi is indicated for the treatment of active rheumatoid arthritis in adults when the response to disease-modifying antirheumatic drugs (DMARDs) including methotrexate (unless contraindicated) has been inadequate. Erelzi 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. Etanercept, 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.

Juvenile idiopathic arthritis

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.

Psoriatic arthritis

Treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug therapy has been inadequate. Etanercept 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.



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Axial spondyloarthritis

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 non-steroidal 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.

מקרא לעדכונים המסומנים:

- תוספת החמרה – כתב **כחול** – מסומן במרקר צהוב
- תוספת שאינה החמרה – כתב **כחול**
- מידע שהוסר – קו אדום חוצה ~~XXX~~

השינויים העיקריים בעלון לרופא

3. Pharmaceutical Form

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Erelzi® is a biosimilar medicinal product that has been demonstrated to be similar in quality, safety and efficacy to the reference medicinal product Enbrel. Please be aware of any differences in the indications between the biosimilar medicinal product and the reference medicinal product. The biosimilar is not to be switched with the reference medicinal product unless specifically stated otherwise. More detailed information regarding biosimilar medicinal products is available on the website of the Ministry of Health: <https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Registration/Pages/Biosimilars.aspx>

4.4 Special warnings and precautions for use

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Paediatric population

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~~*Inflammatory bowel disease (IBD) and uveitis in patients with juvenile idiopathic arthritis (JIA)
There have been reports of IBD and uveitis in JIA patients being treated with etanercept (see section 4.8).*~~

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions are injection site reactions (such as pain, swelling, itching, reddening and bleeding at the puncture site), infections (such as upper respiratory infections, bronchitis, bladder infections and skin infections), **headache**, allergic reactions, development of autoantibodies, itching, and fever.

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Tabulated list of adverse reactions

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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)
Nervous system disorders	Headache			...		

Description of selected adverse reactions

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Paediatric population

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~~There have been reports of inflammatory bowel disease and uveitis in JIA patients being treated with etanercept from post-marketing sources, including a very small number of cases indicating a positive rechallenge (see section 4.4).~~

השינויים העיקריים בעלונים לצרכן: מזרק מוכן לשימוש, עט מוכן לשימוש

לתשומת ליבך,

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- ארלזי הינו תכשיר ביו-סימילאר. למידע נוסף על תכשירי ביו-סימילאר יש לפנות לאתר משרד הבריאות <https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Registration/Pages/Biosimilars.aspx>

אזהרות מיוחדות בנוגע לשימוש בארלזי

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ילדים ומתבגרים

- ארלזי אינו מיועד לשימוש בילדים ומתבגרים השוקלים מתחת ל-62.5 קילוגרם.

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~~ספר לרופא אם הילד סובל מעוויתות בבטן וכאבי בטן, שלשול, ירידה במשקל או צואה דמית. דווחו מקרים של מחלת מעי דלקתית בילדים החולים בדלקת מפרקים אידיופתית ומטופלים בארלזי.~~

4. תופעות לוואי

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תופעות לוואי נוספות

תופעות לוואי שכיחות מאוד (עשויות להופיע ביותר מ- 1 מכל 10 אנשים):

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• **כאב ראש**

העלון לרופא והעלונים לצרכן נשלחו לפרסום במאגר התרופות באתר משרד הבריאות:

<https://data.health.gov.il/drugs/index.html#!/byDrug>

כמו כן ניתן לקבלם מודפסים על ידי פניה לחברת נוברטיס ישראל בע"מ.

לעדכוןכם בברכה,

לריסה בבוכה

רוקחת ממונה חטיבת סנדוז

נוברטיס ישראל בע"מ