SANDOZ

Erelzi™
etanercept

פברואר 2024

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

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

Erelzi® 25	**Erelzi® 50**
etanercept 25 mg / 0.5 ml	etanercept 50 mg / 1 ml
Solution for injection in pre-filled syringe	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 rhematoid 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

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peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease.

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.

השינויים העיקריים בעלון לרופא

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 enteracept has been detected at low levels ~~-~~in human milk. Enteracept could be considered for use during ~~, a decision must be made whether to discontinue~~ breast-feeding ~~or to discontinue Erelzi 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).

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4.8 Undesirable effects

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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)
Infections and infestations	Infection (including upper respiratory tract infection, bronchitis, cystitis, skin infection)*		Serious infections (including pneumonia, cellulitis, arthritis bacterial, sepsis and parasitic infection)*	Tuberculosis, opportunistic infection (including invasive fungal, protozoal, bacterial, atypical mycobacterial, viral infections, and Legionella)*		Hepatitis B reactivation, listeria
Neoplasms benign, malignant and unspecified (including cysts and polyps)			Non-melanoma skin cancers* (see section 4.4)	Malignant melanoma (see section 4.4), lymphoma, leukaemia		Merkel cell carcinoma (see section 4.4), Kaposi Sarcoma
Blood and lymphatic system disorders			Thrombocytopenia, anaemia, leukopenia, neutropenia	Pancytopenia*	Aplastic anaemia*	Histiocytosis haematophagic (macrophage activation syndrome)*
Immune system disorders		Allergic reactions (see Skin and subcutaneous tissue disorders), autoantibody formation*	Vasculitis (including anti-neutrophilic cytoplasmic antibody positive vasculitis)	Serious allergic/ anaphylactic reactions (including angioedema, bronchospasm), sarcoidosis		Worsening of symptoms of dermatomyositis

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			CNS demyelinating events suggestive of multiple sclerosis or localised demyelinating conditions, such as optic neuritis and transverse myelitis (see section 4.4), peripheral demyelinating events, including Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, demyelinating polyneuropathy, and multifocal motor neuropathy (see section 4.4), seizure		
Eye disorders			Uveitis, scleritis			
Cardiac disorders			Worsening of cardiac failure congestive (see section 4.4)	New onset cardiac failure congestive (see section 4.4)		
Respiratory, thoracic, and mediastinal disorders				Interstitial lung disease (including pneumonitis and pulmonary fibrosis)*		
Gastrointestinal disorders			Inflammatory bowel disease			

Hepatobiliary disorders			Elevated liver enzymes*	Autoimmune hepatitis*		
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	Toxic epidermal necrolysis	
Musculoskeletal and connective tissue disorders				Cutaneous lupus erythematosus, subacute cutaneous lupus erythematosus, lupus-like		
Renal and urinary disorders						Glomerulonephritis
General disorders and administration site conditions	Injection site reactions (including bleeding, bruising, erythema, itching, pain, swelling)*	Pyrexia				
~~Gastrointestinal disorders~~			~~Inflammatory bowel disease~~			

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7. Instructions for preparing and administration of Erelzi injection

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Caution: Keep the syringe out of the sight and reach of children.

1. Do not open the outer box until you are ready to use this medicine.
2. Do not use this medicine if the seal of the blister is broken, as it may not be safe for you to use.
3. Do not shake the syringe.
4. Never leave the syringe lying around where others might tamper with it.
5. The pre-filled syringe has a needle guard that will be activated to cover the needle after the injection is finished. The needle guard will help to prevent needle stick injuries to anyone who handles the pre-filled syringe.

Be careful not to touch the needle guard wings before use. By touching them, the needle guard may be activated too early.

6. Do not remove the needle cap until just before you give the injection.
7. The syringe cannot be re-used. Dispose of the used syringe immediately after use in a sharps container.
8. Do not use if the syringe has been dropped onto a hard surface or dropped after removing the needle cap.

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

אזהרות מיוחדות בנוגע לשימוש בארלזי

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- **יש לפנות לרופא מיד אם** אתה/הילד חש בתגובה אלרגית כגון לחץ בחזה, צפצופים, סחרחורת או פריחה. במקרה זה אין להמשיך בהזרקת ארלזי.

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היריון והנקה

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יש לפנות לרופא אם את רוצה להניק במהלך הטיפול עם ארלזי . ~~אין להניק במהלך הטיפול בארלזי, מכיוון שארלזי עובר לחלב אם.~~

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4. תופעות לוואי

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תופעות לוואי ששכיחותן אינה ידועה:

- סרטן עור מסוג קרצינומה על שם מרקל (Merkel cell carcinoma)
- סרקומה על שם קפושי (Kaposi's sarcoma), סרטן נדיר הקשור לזיהום בנגיף ההרפס האנושי 8. סרקומה על שם קפושי מופיעה לרוב כנגעים סגולים על העור
- פעילות מוגברת של תאי דם לבנים הקשורים לדלקת (macrophage activation syndrome)
- חזרה של הפטיטיס B
- נזק למסננים הזעירים בתוך הכליות הגורם לתפקוד כלייתי לקוי (גלומרולונפריטיס, דלקת של פקעיות הכליה)
- החמרה במצב הנקרא דרמטומיוסיטיס (דלקת שרירים וחולשה המלווה בפריחה עורית)

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השינויים העיקריים בעלונים לצרכן: מזרק מוכן לשימוש

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מידע בטיחות חשוב

אזהרה: שמור על המזרק מחוץ לטווח ראייתם והישג ידם של ילדים.

1. אל תפתח את אריזת הקרטון החיצונית לפני שאתה מוכן להשתמש בתרופה.
2. אל תשתמש בתרופה אם עטיפת המגשית נקרעה, מכיוון שייתכן שהתרופה אינה בטוחה לשימוש.
3. אל תנער את המזרק.
4. אל תשאיר את המזרק ללא השגחה בסביבה בה אחרים עלולים לגעת בו.
5. למזרק המוכן לשימוש יש מגן מחט שיופעל על מנת לכסות את המחט לאחר סיום ההזרקה. מגן המחט יעזור למנוע פגיעות דקירה בכל מי שמשתמש/עוזר להשתמש במזרק.

אל תיגע בכנפי מגן המחט לפני השימוש. אם תיגע בהן, מגן המחט עלול לפעול מוקדם מידי.

6. אל תסיר את מגן המחט עד לרגע מתן הזריקה.

7. אין לעשות שימוש חוזר במזרק. השלך את המזרק המשומש מיד לאחר השימוש למכל להשלכת חפצים חדים.

7.8. אין לעשות שימוש במזרק אם הוא נפל על משטח קשיח או שנפל לאחר הסרת מכסה המחט.

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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.

לעדכונכם בברכה,

מגר' דפנה סנדובסקי

רוקחת ממונה חטיבת סנדוז

נוברטיס ישראל בע"מ