

01/2021

רוקח/ת יקר/ה, רופא/ה יקר/ה,

אנו שמחים לבשר על התחלת שיווק של תכשיר ביוסימילאר חדש:

**Brenzys 50 mg/ml**

**ברנזיס 50 מ"ג/מ"ל**

**SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE/PEN**

החומר הפעיל:

Etanercept 50 mg/ml

התוויות המאושרות:

Rheumatoid arthritis

Brenzys 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. Brenzys 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. Brenzys, 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 weighing at least 62.5 Kg 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 weighing at least 62.5 Kg 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 weighing at least 62.5 Kg 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. Brenzys 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.

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 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 weighing at least 62.5 Kg who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

לתכשיר קיים כרטיס מידע בטיחותי למטופל. הכרטיס, המאושר על ידי משרד הבריאות, מכיל מידע בטיחותי חשוב שעל המטופל להיות מודע אליו לפני ובמהלך הטיפול.  
העלון לרופא, העלון לצרכן וכרטיס המידע הבטיחותי למטופל נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום, חברת סמסונג ביואפיס ישראל, בטלפון 09-9533333.

ברנזיס מופץ ע"י חברת נובולוג ומשווק ע"י חברת מרק שארפ ודוהם (ישראל – 1996) בע"מ.

בברכה,

מג'ר נעמי שאקו עזרא  
רוקחת ממונה