אוגוסט 2025

Amgevita 100 mg/mL, (adalimumab)
Solution for injection

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי וי, בעלת הרישום, מבקשת להודיעך על רישום של תכשיר חדש **Amgevita 100 mg/mL** ביוסימילאר (biosimilar) לתרופה המקורית Humira (adalimumab) לטיפול בהתוויות המתוארות מטה.

במסגרת זו, חל **שינוי בפורמולציה של אמג'ויטה, שהיא מרוכזת פי 2 מהנוכחית:**

- הפורמולציה הקיימת של 40 מ"ג/0.8 מ"ל **(50 מ"ג/מ"ל)**
- **תוחלף** בפורמולציה המרוכזת החדשה של 40 מ"ג/0.4 מ"ל **(100 מ"ג/מ"ל)**

השינוי מיושם הן עבור העט המוכן לשימוש, (pre-filled pen) והן עבור המזרק המוכן לשימוש ,(pre-filled syringe) תוך שיפור נוחות השימוש למטופלים בזכות הפחתת נפח ההזרקה.

בנוסף, בוצע יישור קו רגולטורי של Amgevita עם כלל ההתוויות המאושרות שהינן זהות לתכשיר המקור, לרבות התוויות לטיפול בילדים.

Rheumatoid arthritis:
AMGEVITA 100 mg/mL in combination with methotrexate is indicated for:
• The treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate.
• The treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.
AMGEVITA 100 mg/mL can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.
AMGEVITA 100 mg/mL has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate.

Polyarticular juvenile idiopathic arthritis:
AMGEVITA 100 mg/mL in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). AMGEVITA 100 mg/mL can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.
AMGEVITA 100 mg/mL has not been studied in patients aged less than 2 years.

Enthesitis-related arthritis:
AMGEVITA 100 mg/mL is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Axial spondyloarthritis:
AMGEVITA 100 mg/mL is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

Axial spondyloarthritis without radiographic evidence of AS:
AMGEVITA 100 mg/mL is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS, but with objective signs of inflammation by radiological and/or laboratory tests including MRI and serum CRP levels, who have had an inadequate response to, or are intolerant to, non-steroidal anti-inflammatory drugs.

Psoriatic arthritis:
AMGEVITA 100 mg/mL is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate.
Adalimumab has been shown to reduce the rate of progression of peripheral joint damage as measured by X-

ray in patients with polyarticular symmetrical subtypes of the disease to improve physical function.

Psoriasis:
AMGEVITA 100 mg/mL is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy.
Pediatric plaque psoriasis:
AMGEVITA 100 mg/mL is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies.

Hidradenitis suppurativa (HS):
AMGEVITA 100 mg/mL is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult and adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy.

Crohn's disease:
AMGEVITA 100 mg/mL is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. AMGEVITA 100 mg/mL is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

Pediatric Crohn's disease:
AMGEVITA 100 mg/mL is indicated for the treatment of moderately to severely active Crohn's disease in pediatric patients (from 6-years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy and corticosteroid, and/or an immunomodulator, or who are intolerant to or have contraindications for such therapies.

Ulcerative colitis:
AMGEVITA 100 mg/mL is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

Pediatric ulcerative colitis:
AMGEVITA 100 mg/mL is indicated for the treatment of moderately to severely active ulcerative colitis in pediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

Uveitis:
AMGEVITA 100 mg/mL is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroids-paring, or in whom corticosteroid treatment is inappropriate.

Pediatric Uveitis:
AMGEVITA 100 mg/mL is indicated for the treatment of chronic non-infectious uveitis in pediatric patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

Intestinal Behcet's disease:
AMGEVITA 100 mg/mL is indicated for the treatment of intestinal Behcet's disease in patients who have had an inadequate response to conventional therapy.

העלונים לרופא ולצרכן המעודכנים נשלחו לפרסום במאגר התרופות באתר משרד הבריאות, וניתן לקבלם גם על-ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה. שירות לקוחות: Medison-CS@medison.co.il טלפון: 5634*

בברכה,
אמג'ן אירופה בי. וי.