

תכשיר ביו-סימילאר חדש

חברת פאדאגיס ישראל סוכנויות בע"מ שמחה להודיעכם שמשרד הבריאות אישר את רישומו של תכשיר הביו-סימילאר החדש **יופלימה** במינון 40 מ"ג.

יופלימה- Yuflyma SOLUTION FOR INJECTION (S.C.)

חומר פעיל: Adalimumab 100 mg / 1 ml

התוויות כפי שאושרו בתעודת הרישום:

Rheumatoid arthritis

Yuflyma 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.

Yuflyma can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

Adalimumab 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.

Juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis

Yuflyma in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years, weighing ≥ 30 Kg, who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).

Yuflyma can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate (for the efficacy in monotherapy see section 5.1).

Adalimumab has not been studied in patients aged less than 2 years.

Enthesitis-related arthritis

Yuflyma is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, weighing > 30 Kg, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Axial spondyloarthritis

Ankylosing spondylitis (AS)

Yuflyma 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

Yuflyma 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 (NSAIDs).

Psoriatic arthritis

Yuflyma 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 and to improve physical function.

Psoriasis

Yuflyma is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy.

Paediatric plaque psoriasis

Yuflyma is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age, weighing > 30 Kg, who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies.

Hidradenitis suppurativa (HS)

Yuflyma is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults and adolescents from 12 years of age, weighing \geq 30 Kg, with an inadequate response to conventional systemic HS therapy.

Crohn's disease

Yuflyma 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. Yuflyma 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.

Paediatric Crohn's disease

Yuflyma is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (from 6 years of age, weighing \geq 40 Kg), 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

Yuflyma 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.

Paediatric ulcerative colitis

Yuflyma is indicated for the treatment of moderately to severely active ulcerative colitis in paediatric 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

Yuflyma 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 corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate.

Paediatric uveitis

Yuflyma is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age, weighing \geq 30 Kg, who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

Intestinal Behcet's disease

Yuflyma is indicated for the treatment of intestinal Behcet's disease in patients who have had an inadequate response to conventional therapy.

העלון לצרכן והעלון לרופא הועברו לפרסום במאגר התרופות שבאתר משרד הבריאות:
<https://israeldrugs.health.gov.il/#!/byDrug>

ברכה,
פאדאגיס ישראל סוכנויות בע"מ