

דצמבר 2020

רופא/ה, רוקח/ת נכבדים,

חברת ניאופרם (ישראל) בע"מ שמחה להודיע על רישומו של התכשיר IDACIO[®]

IDACIO[®]

אידיסיו

Active Ingredient: Adalimumab 40 mg/0.8 ml

Dosage & Administration forms: Solution for injection, S.C

Approved Therapeutic Indications:

Rheumatoid arthritis

Idacio 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.

Idacio 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.

Axial spondyloarthritis

Ankylosing spondylitis (AS): Idacio 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: Idacio 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

Idacio 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 (see Section 5.1) and to improve physical function.

Psoriasis

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

Hidradenitis suppurativa (HS)

Idacio is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy (see sections 5.1 and 5.2).

Crohn's disease

Idacio 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. Idacio 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.

Ulcerative colitis

Idacio 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.

Uveitis

Idacio 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.

Intestinal Behcet's disease

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

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יצרן:

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בעל הרישום:

העלונים לרופא ולצרין כפי שאושרו על ידי משרד הבריאות הישראלי מצורפים להודעתנו להלן. העלונים לרופא ולצרין נשלחו למשרד הבריאות לצורך העלאתם למאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום: ניאופרם (ישראל) בע"מ, רח' השילוח 6 ת.ד. 7063 פתח-תקווה טלפון: 03-9373737.

בכבוד רב ובברכה,

ילנה קפלן

רוקחת ממונה

ניאופרם (ישראל) בע"מ