

פברואר 2021

רופא/ה רוקח/ת נכבד/ה,

תכשיר ביו-סימילארי חדש לאדאלימומאב

חברת **נוברטיס ישראל בע"מ** שמחה לבשר על רישומו של התכשיר הביו-סימילארי החדש:

Hyrimoz - היירימוז

המכיל את החומר הפעיל adalimumab 40mg/0.8ml וזמין במזרק מוכן לשימוש או בעט "סנסורדי" מוכן לשימוש (תמיסה להזרקה – solution for injection)

העט והמזרק מכילים, כל אחד, כמות כוללת של 40 מ"ג חומר פעיל.

המנה של 40 מ"ג ניתנת בפורמולציה שריכוזה 50mg/ml (40mg/0.8ml). לציין כי תכשיר המקור הרשום ומשווק בישראל, ניתן בפורמולציה שריכוזה 100mg/ml (40mg/0.4ml).

ההתוויות כפי שאושרו בתעודת הרישום:

Rheumatoid arthritis

Hyrimoz 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.

Hyrimoz 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):

Hyrimoz 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:



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ת.ד. 7126, תל אביב

טלפון: 03-9201111 פקס: 03-9229244

Hyrimoz 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

Hyrimoz 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

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

Hidradenitis suppurativa (HS)

Hyrimoz 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.

Crohn's disease

Hyrimoz 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. Hyrimoz 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

Hyrimoz 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

Hyrimoz 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

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

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:

<https://data.health.gov.il/drugs/index.html#/byDrug>

03-9201111 בטלפון בע"מ, נוברטיס ישראל בע"מ, נוברטיס ישראל בע"מ

לעדכונכם בברכה,

מגר' דפנה סנדובסקי

רוקחת ממונה חטיבת סנדוז,

נוברטיס ישראל בע"מ