

05/2021

רופא/ה, רוקח/ת נכבד/ה,
חברת ניאופרם (ישראל) 1996 בע"מ מבקשת להודיעך על עדכון העלון לצרכן והעלון לרופא של התכשיר:

IDACIO

אידיסיו

Solution for injection

תמיסה להזרקה

Subcutaneous use (S.C)

לשימוש תת עורי

Adalimumab 40 mg /0.8 ml

החומר הפעיל וכמותו:

Fresenius Kabi, Hafnerstrasse 36, A-8055 Graz, Austria

שם היצרן וכתובתו:

ניאופרם (ישראל) 1996 בע"מ, ת.ד. 7063, השילוח 6 פתח תקווה

שם בעל הרישום וכתובתו:

להלן נוסח ההתוויה המאושר לתכשיר:

- **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 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.

- **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.

העדכונים המהותיים בעלון לרופא:

4.2 Posology and method of administration

[...]

Intestinal Behcet's disease

The initial dose of Idacio for adult intestinal Behcet's disease patients is 160 mg as subcutaneous injection. The initial dose is followed by 80 mg two weeks later. From four weeks after the initial dose, 40 mg is administered ~~begin 40 mg~~ every other week.

Idacio should be used when the signs and symptoms caused by intestinal Behcet's disease remain clearly even evident if patients after ~~have~~ appropriate treatment with existing drug (steroids or immunosuppressant/modulator, etc.).

Continued therapy with the same regimen should be carefully reconsidered in a patient not responding such as clinical symptoms and/or endoscopic findings within 12 weeks of treatment.

4.8 Undesirable effects

[...]

Table 6

Undesirable Effects

System Organ Class	Frequency	Adverse Reaction
Neoplasms benign, malignant and unspecified (including cysts and polyps)*	Not known	[...] <u>Kaposi's sarcoma</u>

העדכונים המהותיים בעלון לצרכן:

4. תופעות לוואי

תופעות לוואי ששכיחותן אינה ידועה (התדירות אינה ניתנת להערכה מתוך המידע הקיים):

[...]

• סרקומה על שם קפושי, סרטן נדיר הקשור לזיהום בנגיף ההרפס האנושי 8. סרקומה על שם קפושי מופיעה לרוב כנגעים סגולים על העור

- השינויים המסומנים במכתב זה - הטקסט עם קו תחתון הוסף לעלון ואילו הטקסט המחוקק בקו חוצה נגרע ממנו. הסימונים בצהוב הינם החמרות במידע הבטיחותי .
- **העדכונים המשמעותיים ביותר מופיעים במכתב זה, אך קיימים עדכונים נוספים. מצ"ב העלוני המעודכנים – יש לקרוא אותם במלואם.**
- העלון לרופא ולצרכן המעודכנים נשלחו למשרד הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד הבריאות.
- ניתן לקבל את העלוני מודפסים על ידי פניה ישירה לבעל הרישום:
ניאופרם (ישראל) בע"מ, רח' השילוח 6, ת.ד. 7063, פתח תקווה 4917001, טלפון: 03-9373737.

בברכה,

ילנה קפלן
רוקחת ממונה
ניאופרם (ישראל) בע"מ