08-2022

רופא/ה ,רוקח/ת נכבד/ה,

חברת ניאופרם (ישראל) 1996 בע"מ מבקשת להודיעך על עדכון העלון לרופא והעלון לצרכן של התכשיר: **IDACIO**

- עלון התכשיר עודכן ב 08-2022
- טקסט חדש מופיע **בכחול** , טקסט שהוסר מופיע באדום עם ~~קו חוצה~~ .

IDACIO	**אידסיו**
Solution for injection	**תמיסה להזרקה**
Subcutaneous use (S.C)	**לשימוש תת עורי**

<u>החומר הפעיל וכמותו:</u> Adalimumab 40 mg /0.8 ml

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 בעלון לרופא:

6.4 Special precautions for storage

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A single Idacio pre-filled syringe or pre-filled pen may be stored at temperatures up to a maximum of 25°C for a single period of up to ~~14~~ 28 days.
The pre-filled syringe or the pre-filled pen must be protected from light, and discarded if not used within the ~~14~~ 28-day period.

העדכונים בעלון לצרכן:

<u>תנאי אחסון חלופיים:</u>

- בעת הצורך (למשל כאשר אתה בנסיעה), ניתן לאחסן עט **אחד** מוכן להזרקה בטמפרטורה מתחת ל-25°C לתקופה מקסימאלית של עד 28 ~~14~~ ימים - יש להגן על העט מפני אור.
- לאחר הוצאת העט מהמקרר והעברתו לאחסון בטמפרטורה מתחת ל- 25°C **יש להשתמש בעט בתוך 28 ~~14~~ ימים או להשליכו**, אפילו אם הוחזר למקרר.
- יש לתעד את התאריך שבו הוצא העט מן המקרר לראשונה ואת התאריך שלאחריו יש להשליך את העט.

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הוראות אחסון:

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- אם נדרש, למשל לצורך נסיעה, ניתן לאחסן עט מוכן להזרקה בודד בטמפרטורת החדר עד 28 ~~14~~ ימים.
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- העלונים נשלחו למשרד הבריאות לצורך העלאתם למאגר התרופות שבאתר משרד הבריאות.

- ניתן לקבל עלון זה מודפס על ידי פניה ישירה לבעל הרישום: ניאופרם (ישראל) 1996 בע"מ, בניין ניאופרם, רח' השילוח 6, ת.ד. 7063, פתח תקווה 4917001. טלפון: 03-9373737, פקס: 03-9373770.

בברכה,

עוז וולך, רוקח ממונה של בעל הרישום

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