יולי 2024

רופא/ה רוקח/ת נכבד/ה,

חברת פאדאגיס ישראל סוכנויות בע"מ מבקשת להודיע על עדכון העלונים לצרכן ולרופא של התכשיר בהמשך לאישור משרד הבריאות לנפח הזרקה נוסף של 80 mg/0.8 ml ולעדכון תנאי האחסון החלופיים של התכשיר ב-25°C מ-30 ל-31 ימים.

יופלימה- Yuflyma

SOLUTION FOR INJECTION (S.C.)

חומר פעיל: Adalimumab 100 mg / 1 ml

<u>התוויות כפי שאושרו בתעודת הרישום:</u>

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
<u>Polyarticular juvenile idiopathic arthritis</u>
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 <u>≥</u> 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.

<u>Enthesitis-related arthritis</u>
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
<u>Ankylosing spondylitis (AS)</u>
Yuflyma is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

<u>Axial spondyloarthritis without radiographic evidence of AS</u>
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 ≥ 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 ≥ 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 ≥ 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.

מהות העדכון:
בהודעה זו מסומנים העדכונים המהותיים ברקע צהוב. העלונים כוללים גם עדכונים נוספים.
העלונים המעודכנים לצרכן ולרופא נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://israeldrugs.health.gov.il/#!/byDrug

בברכה,
פאדאגיס ישראל סוכנויות בע"מ

עלון לרופא

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition- Adalimumab 100 mg/ 1 ml:

Yuflyma solution for injection in pre-filled syringe

40 mg: Each 0.4ml single dose pre-filled syringe contains 40 mg of adalimumab.

80 mg: Each 0.8ml single dose pre-filled syringe contains 80 mg of adalimumab.

Yuflyma solution for injection in pre-filled pen

40 mg: Each 0.4ml single dose pre-filled pen contains 40 mg of adalimumab.

80 mg: Each 0.8ml single dose pre-filled pen contains 80 mg of adalimumab.

עדכונים נוספים בוצעו בסעיף 4.2.

6.4 Special precautions for storage

A single Yuflyma pre-filled syringe or pre-filled pen may be stored at temperature up to a maximum of 25°C for a period of up to ~~30~~ 31 days.

The pre-filled syringe or pre-filled pen must be protected from light and discarded if not used within the ~~30~~31-day period.

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6.5 Nature and contents of Container

Yuflyma solution for injection in pre-filled syringe (PFS):

Packs of 40 mg:

- 1 pre-filled syringe (0.4 ml sterile solution) with 2 alcohol pads.
- 2 pre-filled syringes (0.4 ml sterile solution), each with 2 alcohol pads.
- 4 pre-filled syringes (0.4 ml sterile solution), each with 4 alcohol pads.
- 6 pre-filled syringes (0.4 ml sterile solution), each with 6 alcohol pads.

Pack of 80 mg:

- 1 pre-filled syringe (0.8 ml sterile solution) with 2 alcohol pads.

Yuflyma solution for injection in pre-filled syringe with safety guard (PFS-S).

Packs of 40 mg:

- 1 pre-filled syringe with needle guard (0.4 ml sterile solution) with 2 alcohol pads.
- 2 pre-filled syringes with needle guard (0.4 ml sterile solution), each with 2 alcohol pads.
- 4 pre-filled syringes with needle guard (0.4 ml sterile solution), each with 4 alcohol pads.
- 6 pre-filled syringes with needle guard (0.4 ml sterile solution), each with 6 alcohol pads.

Pack of 80 mg:

- 1 pre-filled syringe with needle guard (0.8 ml sterile solution) with 2 alcohol pads.

Yuflyma solution for injection in pre-filled pen (Auto Injector- AI):

Packs of 40 mg:

- 1 pre-filled pen (0.4 ml sterile solution), with 2 alcohol pads.
- 2 pre-filled pens (0.4 ml sterile solution), each with 2 alcohol pads.
- 4 pre-filled pens (0.4 ml sterile solution), each with 4 alcohol pads.
- 6 pre-filled pens (0.4 ml sterile solution), each with 6 alcohol pads.

Packs of 80 mg:

- 1 pre-filled pen (0.8 ml sterile solution), with 2 alcohol pads.
- 3 pre-filled pens (0.8 ml sterile solution), each with 4 alcohol pads.

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עלון לצרכן

יופלימה
40 מ"ג
80 מ"ג
תמיסה להזרקה בעט מוכן להזרקה
חומר פעיל וריכוזו: אדאלימומאב 100 מ"ג/מ"ל
כל עט של יופלימה 40 מ"ג מוכן להזרקה מכיל:
אדאלימומאב 40 מ"ג ב- 0.4 מ"ל adalimumab 40 mg/0.4 ml
כל עט של יופלימה 80 מ"ג מוכן להזרקה מכיל:
אדאלימומאב 80 מ"ג ב- 0.8 מ"ל adalimumab 80 mg/0.8 ml
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5. איך לאחסן את התרופה?
…
תנאי אחסון חלופיים:

- בעת הצורך, ניתן לאחסן עט **אחד** מוכן להזרקה בטמפרטורה מקסימלית של 25°C עד ל- ~~30~~ 31 ימים. יש להגן על העט המוכן להזרקה מפני אור ולהשליכו אם לא נעשה בו שימוש במהלך ~~30~~ 31 הימים מיום הוצאתו מהמקרר.

6. מידע נוסף
…
כיצד נראית התרופה ומה תוכן האריזה?
…

- התמיסה הינה תמיסה סטרילית של אדאלימומאב (adalimumab) בנפחים הבאים:
  40 מ"ג/ 0.4 מ"ל
  80 מ"ג/ 0.8 מ"ל

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יופלימה (80 מ"ג) תמיסה להזרקה בעט מוכן להזרקה (Auto Injector- AI):

- 1 עט מוכן להזרקה (0.8 מ"ל תמיסה סטרילית), עם 2 פדי אלכוהול.
- 3 עטים מוכנים להזרקה (0.8 מ"ל תמיסה סטרילית), עם 4 פדי אלכוהול.

ייתכן שלא כל גודלי האריזות ישווקו.
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