רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

Humira

יומירה

Solution for injection

adalimumab 100mg/1ml

חברת AbbVie Biopharmaceuticals Ltd. מתכבדת להודיע כי משרד הבריאות אישר תוספת של משטר מינון חלופי -

80 מ"ג פעם בשבועיים כמשטר מינון חלופי למינון המאושר כיום של 40 מ"ג פעם בשבוע בהתוויות הבאות:

Rheumatoid arthritis, Crohn's disease, Paediatric Crohn's disease, Psoriasis, Hidradenitis suppurativa, Ulcerative colitis, Paediatric plaque psoriasis, Adolescent hidradenitis suppurativa (from 12 years of age, weighing at least 30 kg)

העלון לרופא התעדכן בסעיפים מינונים ונתונים פרמקוקינטים (הוספה מסומן בקו תחתון, מחיקה מסומנת בקו אמצעי).

ההתוויות המאושרות לתכשיר:

Rheumatoid arthritis

Humira 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.

Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

Humira 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

Polyarticular juvenile idiopathic arthritis

Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Humira 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). Humira has not been studied in patients aged less than 2 years.

Enthesitis-related arthritis

Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Axial spondyloarthritis

Ankylosing spondylitis (AS):

Humira 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:

Humira 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

Humira 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. Humira 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

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

Paediatric plaque psoriasis

Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies.

Hidradenitis suppurativa (HS)

Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult and adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy.

Crohn’s disease

Humira 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. Humira 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

Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients (from 6- years of age) 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

Humira 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

Humira 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

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

Paediatric Uveitis

Humira is indicated for the treatment of chronic non-infectious uveitis in paediatric patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

העלון לרופא עודכן בסעיפים הבאים:

4.2 Posology and method of administration

Rheumatoid arthritis

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In monotherapy, some patients who experience a decrease in their response to Humira 40 mg every other week may benefit from an increase in ~~dose intensity~~ dosage to 40 mg adalimumab every week or 80 mg every other week.

Psoriasis

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Beyond 16 weeks, patients with inadequate response to Humira 40 mg every other week may benefit from an increase in ~~dosing frequency~~dosage to 40 mg every week or 80 mg every other week. The benefits and risks of continued 40mg weekly or 80mg every other week~~weekly Humira~~ therapy should be carefully reconsidered in a patient with an inadequate response after the increase in dosing frequency (see section 5.1). If adequate response is achieved with 40 mg every week or 80 mg every other week, ~~an increased dosing frequency~~, the dosage may subsequently be reduced to 40 mg every other week.

Hidradenitis suppurativa

The recommended Humira dose regimen for adult patients with hidradenitis suppurativa (HS) is 160 mg initially at Day 1 (given as four 40 mg or two 80mg injections in one day or as two 40 mg or one 80 mg

injections per day for two consecutive days), followed by 80 mg two weeks later at Day 15 (given as two 40 mg or one 80 mg injections in one day). Two weeks later (Day 29) continue with a dose of 40 mg every week or 80 mg every other week (given as two 40 mg or one 80 mg injections in one day). Antibiotics may be continued during treatment with Humira if necessary. It is recommended that the patient should use a topical antiseptic wash on their HS lesions on a daily basis during treatment with Humira.

Continued therapy beyond 12 weeks should be carefully reconsidered in a patient with no improvement within this time period.

Should treatment be interrupted, ~~40 mg of~~ Humira 40 mg every week or 80 mg every other week may be re-introduced (see section 5.1).

Crohn's disease
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Some patients who experience decrease in their response to Humira 40 mg every other week may benefit from an increase in dosage ~~dosing frequency~~ to 40 mg Humira every week or 80 mg every other week.

Ulcerative colitis

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Some patients who experience decrease in their response to Humira 40 mg every other week may benefit from an increase in dosage ~~dosing frequency~~ to 40 mg Humira every week or 80 mg every other week.

Paediatric plaque psoriasis
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In adolescent patients with inadequate response to Humira 40 mg every other week, an increase in dosage~~dosing frequency~~ to 40 mg every week or 80 mg every other week may be considered.

Adolescent hidradenitis suppurativa (from 12 years of age, weighing at least 30 kg)

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In adolescent patients with inadequate response to Humira 40 mg every other week, an increase in dosage dosing frequency to 40 mg every week or 80 mg every other week may be considered.

Paediatric Crohn's disease
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Patients who experience insufficient response may benefit from an increase in dosage:

- < 40 kg: 20 mg every week
- ≥ 40 kg: 40 mg every week or 80 mg every other week

5.2 Pharmacokinetic properties

Absorption and distribution

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Population pharmacokinetic and pharmacokinetic/pharmacodynamic modelling and simulation predicted comparable adalimumab exposure and efficacy in patients treated with 80 mg every other week when compared with 40 mg every week (including adult patients with RA, HS, UC, CD or Ps, patients with adolescent HS, and paediatric patients ≥ 40 kg with CD).

העלון המעודכן לרופא נשלח למאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום, AbbVie Biopharmaceuticals Ltd, רחוב החרש 4, הוד השרון או בטלפון 09 – 7909600.

בברכה,
חופית שוורץ - רוקחת ממונה