רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

Humira

יומירה

Solution for injection

adalimumab 100mg/1ml

חברת AbbVie Biopharmaceuticals Ltd. מבקשת להודיע כי העלון לרופא של התכשיר עודכן. בהודעה זו מצוינים סעיפים בהם נעשה שינוי מהותי (שינוי שהינו הוספה מסומן בקו תחתון, מחיקה מסומנת בקו אמצעי).
עדכונים נוספים אשר אינם מהותיים, אינם נכללים בהודעה זו.

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 בסעיף הבא:

5.1 Pharmacodynamic properties

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Patients who completed Studies UV I and UV II were eligible to enroll in an uncontrolled long-term extension study with an originally planned duration of 78 weeks. Patients were allowed to continue on study medication beyond Week 78 until they had access to Humira.

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Of the ~~417~~424 subjects included in the uncontrolled long-term extension of Studies UV I and UV II, ~~46~~60 subjects were regarded ineligible (e.g. ~~developed~~ due to deviations or due to complications secondary to diabetic retinopathy, due to cataract surgery or vitrectomy) and were excluded from the primary analysis of efficacy. Of the ~~371~~364 remaining patients, ~~276~~269 evaluable patients (74%) reached 78 weeks of open-label adalimumab treatment. Based on the observed data approach, ~~222~~216 (80.43%) were in quiescence (no active inflammatory lesions, AC cell grade ≤ 0.5+, VH grade ≤ 0.5+) with a concomitant steroid dose ≤ 7.5 mg per day, and ~~184~~178 (66.~~7~~2 %) were in steroid-free quiescence. BCVA was either improved or maintained (< 5 letters deterioration) in 88.~~4~~6% of the eyes at week 78. Data beyond Week 78 were generally consistent with these results but the number of enrolled subjects declined after this time. Overall, among the patients who discontinued the study, ~~prior to week 78, 11~~ 18% discontinued due to adverse events, and ~~5~~8% due to insufficient response to adalimumab treatment.

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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 7909600 – 09.

בברכה,
חופית שוורץ - רוקחת ממונה