

Humira

יומירה

**Solution for injection
Adalimumab 100mg/ml**

חברת AbbVie Biopharmaceuticals Ltd. מבקשת להודיע כי העלון לרופא של התכשיר התעדכן. בהודעה זו מצוינים סעיפים בהם נעשה שינוי מהותי או שינוי המהווה החמרה. מידע שהתווסף מסומן באדום ומידע שהוסר מסומן בכחול.

התכשיר מותווה לטיפול במחלות הבאות (נוסח התוויה מצוי בעלון):

Rheumatoid arthritis, Juvenile idiopathic arthritis, Enthesitis-related arthritis, Axial spondyloarthritis, Psoriatic arthritis, Psoriasis, Paediatric plaque psoriasis, Hidradenitis suppurativa (HS), Crohn's disease, Paediatric Crohn's disease, Ulcerative colitis, Uveitis, Intestinal Behcet's disease, Paediatric Uveitis

העלון לרופא עודכן בסעיף הבא:

4.2 Posology and method of administration

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Intestinal Behcet's disease

The initial dose of Humira 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.

Humira should be used when the signs and symptoms caused by intestinal Behcet's disease remain clearly **ev**~~ident if patients after have~~ appropriate treatment with existing drug (steroids or immunomodulators~~suppressant~~, 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

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5.1 Pharmacodynamic properties

Intestinal Behcet's disease

Phase III Clinical study in Japan

In an open-label and uncontrolled study in **20** patients **Note** with intestinal Behcet's disease who have had an inadequate response to conventional therapy (steroid or **immunomodulator-immunosuppressant**), marked improvement rate at Week 24 (the proportion of the subjects whose global assessment of gastrointestinal symptoms and endoscopic improvement are both ≤ 1) was 45.0% (9/20)⁺.



Common adverse events (at week 52) were nasopharyngitis 9 cases (45.0%), diarrhea, Behcet's syndrome (exacerbation of original disease), contused wound and cough 3 cases (15.0%) each.

[‡]Note) The patients who were diagnosed to have the complete type, incomplete type or suspected according to the diagnostic criteria for Behcet's disease by the research division of the Ministry of Health, Labor and Welfare and were observed to have a typical ulcer of 1 cm or larger in longer diameter in the ileocecal region.

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