



רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

אבוט לבורטוריוז ס.א. מודיעה כי העלון לצרכן והעלון לרופא של התכשיר Humira 40 mg עודכן. בהודעה זו מצוינים סעיפים בהם נעשה שינוי אשר מהווה החמרה או שינוי מהותי. עדכונים נוספים אשר אינם מהווים החמרה או שאינם מהותיים, אינם נכללים בהודעה זו (שינוי שהינו הוספה מסומן בקו תחתון, מחיקה מסומנת בקו אמצעי).

Humira 40 mg
יומירה 40 מ"ג
Solution for Injection
Adalimumab 40 mg / 0.8 ml

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.

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.

Ankylosing spondylitis

Humira is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional 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.

Psoriasis

Humira is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.

Polyarticular juvenile idiopathic arthritis

Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 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.

Humira has not been studied in children aged less than 4 years.



העלון לצרכן עודכן בסעיפים:

פעילות רפואית

מהות השינוי:

לטיפול בדלקת מפרקים שגרונת בילדים ובמתבגרים (Juvenile idiopathic arthritis) מגיל 4 עד 17. יומירה אינו נבדק בילדים שגילם קטן מ-4 שנים

אזהרות

מהת השינוי:

חולים עם דלקת מפרקים שגרונת קשה יותר, שסובלים מן המחלה לאורך זמן, עלולים להיות בעלי סיכון גבוה מן הממוצע לחלות בלימפומה (סוג מסויים של סרטן שפוגע במערכת הלימפטית) ולוקמיה (סוג מסויים של סרטן המשפיע על מח העצם והדם). אם אתה/נוטלת/ יומירה הסיכון שלך עלול לעלות.

בנוסף נצפו מקרים מאד נדירים של סרטן העור שאינו מלנומה בחולים הנוטלים יומירה.

תופעות לוואי

מהות השינוי:

תופעות לוואי עלולות להתרחש עד 4-5 חודשים לפחות אחרי הטיפול האחרון.

מינון והוראות שימוש

מהות השינוי:

תרופה זו אינה מיועדת בדרך כלל לתינוקות ולילדים מתחת לגיל 4 שנים.

העלון לרופא עודכן בסעיפים:

4.2 Posology and method of administration:

מהות השינוי:

During treatment with Humira, other concomitant therapies (e.g., corticosteroids and/or immunomodulatory agents) should be optimised.

Paediatric population:

Polyarticular Juvenile Idiopathic Arthritis

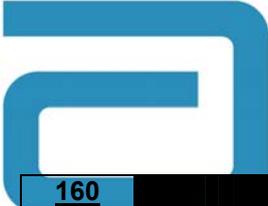
Humira has not been studied in children aged less than 4 years. Limited data are available for Humira treatment in paediatric patients with a weight below 15 kg.

Polyarticular Juvenile Idiopathic Arthritis Age 4 to 12 years

The recommended dose of Humira for patients with polyarticular juvenile idiopathic arthritis, aged 4 -12 years, is 24 mg/m² body surface area up to a maximum single dose of 40 mg adalimumab administered every other week via subcutaneous injection. The volume for injection is selected based on the patients' height and weight (Table 1).

Table 1. Humira Dose in Milliliters (ml) by Height and Weight of Children for Polyarticular Juvenile Idiopathic Arthritis

Height (cm)	Total Body Weight (kg)												
	10	15	20	25	30	35	40	45	50	55	60	65	70
80	0.2	0.3	0.3	0.3									
90	0.2	0.3	0.3	0.4	0.4	0.4							
100	0.3	0.3	0.3	0.4	0.4	0.4	0.5	0.5					
110	0.3	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.5	0.6	0.6		
120	0.3	0.4	0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6	0.6	0.7	0.7
130		0.4	0.4	0.5	0.5	0.5	0.6	0.6	0.6	0.6	0.7	0.7	0.7
140		0.4	0.4	0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.8*
150			0.5	0.5	0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.8*	0.8*



<u>160</u>			<u>0.5</u>	<u>0.5</u>	<u>0.6</u>	<u>0.6</u>	<u>0.7</u>	<u>0.7</u>	<u>0.7</u>	<u>0.8*</u>	<u>0.8*</u>	<u>0.8*</u>	<u>0.8*</u>
<u>170</u>				<u>0.6</u>	<u>0.6</u>	<u>0.6</u>	<u>0.7</u>	<u>0.7</u>	<u>0.8*</u>	<u>0.8*</u>	<u>0.8*</u>	<u>0.8*</u>	<u>0.8*</u>
<u>180</u>					<u>0.6</u>	<u>0.7</u>	<u>0.7</u>	<u>0.8*</u>	<u>0.8*</u>	<u>0.8*</u>	<u>0.8*</u>	<u>0.8*</u>	<u>0.8*</u>

*Maximum single dose is 40 mg (0.8 ml)

Polyarticular Juvenile Idiopathic Arthritis Age 13-17 years:

For adolescents aged 13-17 years, a dose of 40 mg administered every other week is administered as a single dose via subcutaneous injection (regardless of body surface area).

Children and adolescents (aged 13 to 17 years)

Polyarticular Juvenile Idiopathic Arthritis

The recommended dose of Humira for patients with polyarticular juvenile idiopathic arthritis, aged 13 years and above is 40 mg adalimumab administered every other week as a single dose via subcutaneous injection.

4.4 Special warnings and precautions for use

מהות השינוי:

Infection:

Because the elimination of adalimumab may take up to ~~five~~ four months, monitoring should be continued throughout this period.

Other opportunistic infections:

For patients who develop the signs and symptoms such as fever, malaise, weight loss, sweats, cough, dyspnea, and/or pulmonary infiltrates or other serious systemic illness with or without concomitant shock an invasive fungal infection should be suspected and administration of Humira should be promptly discontinued and appropriate antifungal therapy should be initiated.

Neurological events

TNF-antagonists including Humira have been associated in rare instances with new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disease including multiple sclerosis and peripheral demyelinating disease, including Guillain-Barré syndrome. Prescribers should exercise caution in considering the use of Humira in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders.

4.8 Undesirable effects

מהות השינוי:

UNDESIRABLE EFFECTS IN POSTMARKETING SURVEILLANCE AND PHASE IV CLINICAL STUDIES

Neoplasm benign, malignant and unspecified (including cysts and polyps)*	hepatosplenic T-cell lymphoma, <u>leukemia</u>
Immune system disorders*	Anaphylaxis, <u>sarcoidosis</u>
Respiratory, thoracic and mediastinal disorders	pulmonary embolism pleural effusion, <u>pulmonary fibrosis</u>

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העלון המעודכן לרופא נשלח למאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום, אבוט לבורטוריוז ס.א. קריית עתידים בניין 4, ת.ד. 58099 תל אביב או בטלפון 03-7691037.

בברכה,

נעמי רביב
רוקחת ממונה