

11.2024

רופא/ה נכבד/ה  
רוקח/ת נכבד/ה**Olumiant 2mg**  
**Olumiant 4mg**  
Film coated tablets

חברת לילי מבקשת להודיעכם כי העלון לרופא של התכשיר שבנידון עודכן.  
טקסט שהתווסף מודגש בצהוב.  
העלונים המעודכנים לרופא ולצרכן מפורסמים במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים  
על ידי פנייה לבעל הרישום:  
אלי לילי ישראל בע"מ, השיזף 4, רעננה, טל': 09-9606234

בברכה,  
חברת אלי לילי**החומר הפעיל:**

Baricitinib 2&amp;4 mg

**ההתוויה המאושרת לתכשירים:**Rheumatoid arthritis

Olumiant is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Olumiant may be used as monotherapy or in combination with methotrexate (see sections 4.4, 4.5 and 5.1 for available data on different combinations).

Atopic dermatitis

Olumiant is indicated for the treatment of moderate to severe atopic dermatitis in adult and paediatric patients 2 years of age and older who are candidates for systemic therapy.

Alopecia areata

Olumiant is indicated for the treatment of severe alopecia areata in adult patients (see section 5.1).

Juvenile idiopathic arthritis

Olumiant is indicated for the treatment of active juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic disease-modifying antirheumatic drugs (DMARDs):

- Polyarticular juvenile idiopathic arthritis (polyarticular rheumatoid factor positive [RF+] or negative [RF-], extended oligoarticular),
- Enthesitis-related arthritis, and
- Juvenile psoriatic arthritis.

Olumiant may be used as monotherapy or in combination with methotrexate.

**העדכונים העיקריים בעלון לרופא הינם:****Posology and method of administration**

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### Special populations

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#### *Paediatric population (less than 2 years)*

The safety and efficacy of baricitinib in children less than 2 years have not yet been established. No data are available. See section 4.2 above for information on posology in children aged 2 years and older.

#### Juvenile idiopathic arthritis

Only a small number of children aged 2 to 6 have been studied.

The safety and efficacy of baricitinib in children and adolescents less than 18 years of age with alopecia areata have not yet been established. No data are available.