

ינואר 2026

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת אלי לילי ישראל בע"מ מבקשת להודיעכם כי עודכן העלון לרופא של התכשירים OLUMIANT 2 mg ו-OLUMIANT 4 mg.

בהודעה זו נכללים השינויים המהותיים בלבד. שינויים המהווים החמרה מסומנים בצהוב, מידע שהתווסף מסומן בכחול ומידע שהוסר מסומן באדום. ישנם עדכונים נוספים.

העלון לרופא ולצרכן מפורסמים במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום:
אלי לילי ישראל בע"מ, רח' השיזף 4, רעננה, טל': 09-9606234

בברכה,
ליאת אטיאס
רוקחת ממונה

שם התכשיר	אולומיאנט 2 מ"ג	אולומיאנט 4 מ"ג
	OLUMIANT 2 mg	OLUMIANT 4 mg
החומר הפעיל	BARICITINIB	
צורת מינון	FILM COATED TABLETS	
ההתוויה המאושרת לתכשיר	<p>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.</p> <p>Atopic Dermatitis Olumiant is indicated for the treatment of moderate to severe atopic dermatitis in adult and pediatric patients 2 years of age and older who are candidates for systemic therapy.</p> <p>Alopecia areata Olumiant is indicated for the treatment of severe alopecia areata in adult patients.</p> <p>Juvenile idiopathic arthritis Baricitinib 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. Baricitinib may be used as monotherapy or in combination with Methotrexate.</p>	

4.4 Special warnings and precautions for use

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Infections

Serious and sometimes fatal infections, including opportunistic infections, have been reported in patients receiving other JAK inhibitors.

Baricitinib is associated with an increased rate of infections such as upper respiratory tract infections compared to placebo (see section 4.8). In rheumatoid arthritis clinical studies, combination with methotrexate resulted in increased frequency of infections compared to baricitinib monotherapy.

The risks and benefits of treatment should be carefully considered prior to initiating baricitinib in patients with active, chronic or recurrent infections (see section 4.2). If an infection develops, the patient should be monitored carefully and therapy should be temporarily interrupted if the patient is not responding to standard therapy. Treatment should not be resumed until the infection resolves.

As there is a higher incidence of infections in the elderly and in the diabetic populations in general, caution should be used when treating the elderly and patients with diabetes. In patients over 65 years of age, baricitinib should only be used if no suitable treatment alternatives are available.

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