12.2024

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&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:

PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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Eli Lilly Israel LTD. 4 HaSheizaf St.
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Adults with atopic dermatitis

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Maintenance of response

To evaluate maintenance of response, ~~1,373~~ 1398 subjects treated with baricitinib for 16 weeks in BREEZE-AD1 (N = ~~541~~566), BREEZE-AD2 (N = 540) and BREEZE-AD7 (N = 292) were eligible to enrol in a long term extension study BREEZE-AD3. Data are available up to ~~68 weeks~~ 4 years (216 weeks) of cumulative treatment ~~for patients from BREEZE-AD1 and BREEZE-AD2, and up to 32 weeks of cumulative treatment for patients from BREEZE-AD7~~. Continued response was observed in patients with at least some response (IGA 0, 1 or 2) after initiating baricitinib.

Dose tapering

In the long-term extension study BREEZE-AD3, patients who had clear, almost clear skin, or mild disease (i.e., IGA 0, 1, or 2) with baricitinib 4 mg once daily were re-randomised at Week 52 to continue 4 mg once daily or reduce the dose to 2 mg once daily. Among patients who reduced the dose to 2 mg, 37 % had an IGA 0, 1, or 2 response and 52 % had an EASI75 response at Week 200. 47 % of patients in this group had an Itch NRS ≥ 4-point improvement at Week 52, and 40 % had this improvement at Week 68. The proportion of patients with a relapse (IGA ≥ 3) was lower in the subgroup of patients with clear, or almost clear skin (IGA 0 or 1) at start of dose reduction. For those patients who experienced a relapse (IGA ≥ 3) after dose reduction, the majority regained disease control upon retreatment with baricitinib 4 mg.

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