

יוני 2024

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

RINVOQ 15mg, 30mg, 45mg

Prolonged release tablets

(Upadacitinib 15mg, 30mg, 45mg as hemihydrate)

חברת AbbVie Biopharmaceuticals Ltd. מבקשת להודיע כי העלון לרופא והעלון לצרכן של התכשיר התעדכנו. 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:

Rinvoq 15mg

RINVOQ 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 (DMARDs). RINVOQ may be used as monotherapy or in combination with methotrexate.

RINVOQ is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs. RINVOQ may be used as monotherapy or in combination with methotrexate.

RINVOQ is indicated for the treatment of active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy.

RINVOQ is indicated for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.

RINVOQ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.

RINVOQ is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.

Rinvoq 30mg

RINVOQ is indicated for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy.

RINVOQ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.

RINVOQ is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.

Rinvoq 45mg

RINVOQ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.

RINVOQ is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.

העלון לרופא עודכן בסעיפים הבאים:

RINVOQ®

4.7 Effects on ability to drive and use machines

Upadacitinib ~~has no or negligible~~ may have a minor influence on the ability to drive and use machines because dizziness and vertigo may occur during treatment with RINVOQ (see section 4.8).

4.8 Undesirable effects

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System Organ Class	Very common	Common	Uncommon
Nervous system disorders		Headache ^a <u>Dizziness</u>	
<u>Ear and labyrinth disorders</u>		<u>Vertigo</u> ^a	

^a Presented as grouped term

^b In atopic dermatitis trials, the frequency of bronchitis, hypercholesterolaemia, hyperlipidaemia, ALT increased, and AST increased was uncommon.

^c In rheumatologic disease trials, the frequency was common for acne and uncommon for urticaria

^d In ulcerative colitis trials, the frequency was common for acne; abdominal pain was less frequent for upadacitinib than for placebo.

^e Serious hypersensitivity reactions including anaphylactic reaction and angioedema

^f Most events reported as basal cell carcinoma and squamous cell carcinoma of skin

^g In Crohn's disease, the frequency was common for acne, and uncommon for urticaria and weight increased.

^h Pneumonia was common in Crohn's disease and uncommon across other indications.

ⁱ Frequency is based on Crohn's disease clinical trials.

העלון לצרכן עודכן בסעיפים הבאים:

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2. לפני השימוש בתרופה

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נהיגה ושימוש במכונות

לרינבוק אין השפעה או השפעה מוגבלת על היכולת לנהוג ולהשתמש במכונות. אין לנהוג או להשתמש במכונות אם אתה חווה סחרחורת או תחושת סחרור (ורטיגו) בעת נטילת רינבוק עד שהן חולפות.

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4. תופעות לוואי

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תופעות לוואי שכיחות (common) - תופעות שמופיעות ב-10-1 משתמשים מתוך 100

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- תחושת סחרור (ורטיגו)
- סחרחורת

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העלון לרופא ולצרכן נשלחו למאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום, AbbVie Biopharmaceuticals Ltd, רחוב החרש 4, הוד השרון או בטלפון 7909600 – 09.

בברכה,
לובה קוזלובסקי
רוקחת ממונה