

SKYRIZI 75 MG**סקייריזי 75 מ"ג****Solution for injection****Risankizumab 75 mg/ 0.83 ml**

חברת AbbVie Biopharmaceuticals Ltd. מבקשת להודיע כי העalon לרופא של התכשיר עודכן. בהודעה זו מוצאים סעיפים בהם נעשה שינוי מהותי או שינוי המהווה החומרה. מידע שהתווסף מסומן **באדום**, לא הוסר מידע.

ההתוויה המאושרת לתכשיר:

SKYRIZI is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

העלון לרופא עודכן בסעיפים הבאים:**5. PHARMACOLOGICAL PROPERTIES****5.1 Pharmacodynamic properties****IMMHANCE**

IMMHANCE enrolled 507 subjects (407 randomised to risankizumab 150 mg and 100 to placebo). Subjects received treatment at week 0, week 4 and every 12 weeks thereafter. Subjects who were originally on risankizumab and had a sPGA response of clear or almost clear at week 28 were re-randomised to continue risankizumab every 12 weeks through week 88 (with follow-up 16 weeks after last risankizumab dose) or have treatment withdrawn.

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Among subjects who achieved sPGA of clear or almost clear at week 28 and relapsed to sPGA of moderate or severe following withdrawal from risankizumab, 83.7% (128/153) regained sPGA of clear or almost clear after 16 weeks of retreatment. Loss of sPGA of clear or almost clear was observed as early as 12 weeks after a missed dose. Of those subjects who were re-randomised to withdraw from treatment, 80.9% (182/225) relapsed and the median time to relapse was 295 days. No characteristics were identified to predict the time to loss of response or likelihood of regaining response at the individual patient level.

העלון המעודכן לרופא נשלח למאגר התרופות שבמשרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום, AbbVie Biopharmaceuticals Ltd, רחוב החרש 4, הוד השרון או בטלפון 09 - 7909600.

בברכה,

חויפת שורץ
רוקחת ממונה