

אוק' 2021

רופא/ה נכבד/ה
חוקח/ת נכבד/ה

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא ולצרכן של התכשיר:
Remicade – infliximab - 137-18-29865-05

הרשום להתוויות:

Adult:

- Crohn's disease:

Treatment of moderate to severe active Crohn's disease in patients who have not responded despite of a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant. Treatment of fistulising Crohn's disease in patients who have not responded despite of a full and adequate course of therapy with conventional treatment.

Paediatric Crohn's disease:

Remicade is indicated for: Treatment of severe active crohn's disease in paediatric patients aged 6 to 17 years who have not responded to conventional therapy including a corticosteroid an immunomodulator and primary nutrition therapy or who are intolerant to or have contraindications for such therapies. Remicade has been studied only in combination with conventional immunosuppressive therapy

Ankylosing spondylitis:

Remicade is indicated for: treatment of ankylosing spondylitis in patients who have severe axial symptoms elevated serological markers of inflammatory activity and who have responded inadequately to conventional therapy.

Psoriatic arthritis:

Remicade is indicated for: Treatment of active and progressive psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate.

Remicade should be administered: either in combination with methotrexate or alone in patients who show intolerance to methotrexate or for whom methotrexate is contraindicated.

- Remicade has been shown to improve physical function in patients with psoriatic arthritis and to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease.

Rheumatoid arthritis:

Remicade in combination with methotrexate is indicated for the reduction of signs and symptoms as well as the improvement in physical function in: Patients with active disease when the response to disease-modifying drugs including methotrexate has been inadequate. Patients with severe active and progressive disease not previously treated with methotrexate or other DMARDs. In this these patient populations a reduction in the rate of the progression of joint damage as measured by x-ray has been demonstrated

- Psoriasis:

Remicade is indicated for: Treatment of moderate to severe plaque psoriasis in adults who failed to respond to or who have a contraindication to or are intolerant to other systemic therapy including cyclosporine methotrexate or PUVA.

Ulcerative colitis:

Remicade is indicated for: Treatment of moderately to severely active ulcerative colitis in patients who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA or who are intolerant to or have medical contraindications for such therapies.

Paediatric ulcerative colitis:

Remicade is indicated for treatment of severely active ulcerative colitis, in paediatric patients aged 6 to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6 MP or AZA, or who are intolerant to or have medical contraindications for such therapies

השינויים המהותיים בעלון לרופא מופיעים בסעיפים הבאים:

4.8 Undesirable effects

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Metabolism and nutrition disorders

Uncommon: Dyslipidaemia

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השינויים המהותיים בעלון לצרכן מופיעים בסעיפים הבאים:

4. תופעות לוואי

תופעות לוואי שאינן שכיחות (uncommon) - תופעות שמופיעות ב-10-1 משתמשים מתוך 1,000:

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שינויים ברמות כולסטרול ושומנים בדם

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העלון לרופא והעלון לצרכן נשלחו לפרסום במלואם למאגר התרופות שבאתר משרד הבריאות. כמו כן, ניתן לקבלם מודפסים בפניה אלינו לטלפון 09-9591111.

בברכה,

צפריר כהן

רוקח ממונה