

חברת פאדאגיס ישראל סוכנויות בע"מ מבקשת להודיע על עדכון העלונים לצרכן ולרופא של התכשיר:

רמסימה 100 מ"ג תוך-ורידי / REMSIMA 100 MG I.V.

החומר הפעיל בתכשיר וחוזקו: Infliximab 100 mg/vial

ההתוויה הרשומה לתכשיר בישראל :

* Rheumatoid arthritis:

Remsima, in combination with methotrexate, is indicated for the reduction of signs and symptoms as well as the improvement in physical function in:

- adult patients with active disease when the response to disease modifying antirheumatic drugs (DMARDs), including methotrexate, has been inadequate.
- adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs.

In these patient populations, a reduction in the rate of the progression of joint damage, as measured by X ray, has been demonstrated.

* Ankylosing spondylitis:

Remsima is indicated for treatment of severe, active ankylosing spondylitis, in adult patients who have responded inadequately to conventional therapy.

* Psoriatic arthritis:

Remsima is indicated for treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate.

* Remsima should be administered:

- in combination with methotrexate
- or alone in patients who show intolerance to methotrexate or for whom methotrexate is contraindicated.

Infliximab 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.

* Psoriasis:

Remsima is indicated for treatment of moderate to severe plaque psoriasis in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen ultra-violet A (PUVA)

* Adult Crohn's disease

Remsima is indicated for treatment:

- of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.
- treatment of fistulising, active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy).

* Ulcerative colitis

Remsima is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6 mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.



Paediatric Crohn's disease

Remsima is indicated for treatment of severe, active Crohn's disease in children and adolescents 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. Infliximab has been studied only in combination with conventional immunosuppressive therapy.

Paediatric ulcerative colitis

Remsima is indicated for treatment of severely active ulcerative colitis in children and adolescents 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.

מהות העדכון:

בהודעה זו מסומנים עדכוני בטיחות בהתאם לעלוני האסמכתא ברקע צהוב.
העלונים כוללים גם עדכונים נוספים.

העלונים המעודכנים לצרכן ולרופא נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
<https://israeldrugs.health.gov.il/#!/byDrug>

בברכה,
פאדאגיס ישראל סוכנויות בע"מ

עלון לרופא

4.4 Special warnings and precautions for use

[...]

Others

There is limited safety experience of infliximab treatment in patients who have undergone surgical procedures, including arthroplasty. The long half-life of infliximab should be taken into consideration if a surgical procedure is planned. A patient who requires surgery while on infliximab should be closely monitored for infections **infectious and non-infectious complications**, and appropriate actions should be taken (see section 4.8).

[...]

Polysorbate 80 content

Remsima 100 mg I.V. contains 0.50 mg of polysorbate 80 (E433) in each dosage unit which is equivalent to 0.05 mg/ml. Polysorbates may cause allergic reactions.

[...]

4.8 Undesirable effects

[...]

Table 1

Undesirable effects in clinical studies and from post-marketing experience

[...]

Injury, poisoning, and procedural complications

Not known: Post-procedural complication (including infectious and non-infectious complications)

[...]

עלון לצרכן

2. לפני השימוש בתרופה

[...]

רמסימה 100 מ"ג תוך ורידי מכילה פוליסורבט 80

תרופה זו מכילה בכל יחידת מינון 0.50 מ"ג פוליסורבט 80 (E433) שהינם שווי ערך ל-0.05 מ"ג/מ"ל. פוליסורבטים עלולים לגרום לתגובות אלרגיות. ספר לרופא אם יש לך אלרגיות ידועות.

[...]

4. תופעות לוואי

[...]

תופעות לוואי ששכיחותן אינה ידועה (תופעות ששכיחותן טרם נקבעה)

[...]

· בעיות בעקבות הליך רפואי (כולל בעיות זיהומיות ולא זיהומיות)

[...]