אוגוסט 2025

רופא/ה רוקח/ת נכבד/ה,

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

REMSIMA 120 MG/ML S.C. / רמסימה 120 מ"ג/מ"ל תת-עורי

החומר הפעיל בתכשיר וחוזקו: Infliximab 120 mg/ml

<u>ההתוויה הרשומה לתכשיר בישראל :</u>

<u>Rheumatoid arthritis</u>:
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.

<u>Crohn's disease</u>
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).

<u>Ulcerative colitis</u>
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.

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

<u>Psoriatic arthritis</u>
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 ciclosporin, methotrexate or psoralen ultra-violet A (PUVA).

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 infectio~~n~~us and non-infectious complications, and appropriate actions should be taken (see section 4.8).

[...]

4.8 Undesirable effects

[...]

Table 1

Adverse reactions in clinical studies and from post-marketing experience of ~~intravenous~~ infliximab

Infections and infestations	
Very common:	Viral infection (e.g. influenza, herpes virus infection, COVID-19*).

[...]

Investigations	
Uncommon:	Autoantibody positive, weight increased[1].
[...]	
Injury, poisoning, and procedural complications	
Not known:	Post-procedural complication (including infectious and non-infectious complications).

* COVID-19 was seen with the SC administered Remsima

** including bovine tuberculosis (disseminated BCG infection), see section 4.4

[1] At month 12 of the controlled period for adult clinical trials across all indications, the median weight increase was 3.50 kg for infliximab-treated subjects vs. 3.00 kg for placebo-treated subjects. The median weight increase for inflammatory bowel disease indications was 4.14 kg for infliximab-treated subjects vs. 3.00 kg for placebo-treated subjects, and the median weight increase for rheumatology indications was 3.40 kg for infliximab-treated subjects vs. 3.00 kg for placebo-treated subjects.

עלון לצרכן

[...]

4. תופעות לוואי

[...]

תופעות לוואי לא שכיחות: יכולות להופיע אצל עד אחד מבין 100 משתמשים

[...]

- עלייה במשקל (עבור מרבית המטופלים, העלייה במשקל הייתה קטנה).

[...]

תופעות לוואי ששכיחותן אינה ידועה: התדירות אינה יכולה להיקבע מהמידע הקיים

[...]

- בעיות בעקבות הליך רפואי (כולל בעיות זיהומיות ולא זיהומיות).

[...]