אפריל 2022

רופא/ה רוקח/ת נכבד/ה,

חברת פאדאגיס מבקשת ליידע אתכם על עדכון העלון לרופא של התכשיר:

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

החומר הפעיל בתכשיר וחוזקו: Infliximab 100 mg/vial

<u>התוויה הרשומה לתכשיר בישראל :</u>

* 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.

מהות העדכון:
עדכוני בטיחות ועדכוני נוסח בהתאם לעלון האסמכתא וכן התאמה לפורמט העלונים הנדרש לפי הנחיות משרד הבריאות.

העלון המעודכן לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות: http://www.health.gov.il

בברכה,
פאדאגיס ישראל סוכנויות בע"מ

עלון לרופא

4.2 Posology and method of administration

[…]
It is important to check the product labels to ensure that the correct formulation (intravenous or subcutaneous) is being administered to the patient, as prescribed. Remsima subcutaneous formulation is not intended for intravenous administration and should be administered via a subcutaneous injection only.
[…]

4.4 Special warnings and precautions for use

[…]
Infant exposure via breast milk
Administration of a live vaccine to a breastfed infant while the mother is receiving infliximab is not recommended unless infant infliximab serum levels are undetectable (see section 4.6).
[…]

4.5 Interaction with other medicinal products and other forms of interaction

[…]
Administration of a live vaccine to a breastfed infant while the mother is receiving infliximab is not recommended unless infant infliximab serum levels are undetectable (see sections 4.4 and 4.6).
[…]

4.6 Fertility, pregnancy and lactation

[…]
Breast-feeding
Limited data from published literature indicate ~~It is unknown whether~~ infliximab has been detected at low levels ~~is excreted~~ in human milk ~~or absorbed systemically after ingestion.~~ at concentrations up to 5% of the maternal serum level Infliximab has also been detected in infant serum after exposure to infliximab via breast milk. While systemic exposure in a breastfed infant is expected to be low because infliximab is largely degraded in the gastrointestinal tract, the administration of live vaccines to a breastfed infant when the mother is receiving infliximab is not recommended unless infant infliximab serum levels are undetectable. Infliximab could be considered for use during breast-feeding.
~~Because human immunoglobulins are excreted in milk, women must not breast feed for at least 6 months after infliximab treatment.~~
[…]

4.8 Undesirable effects

[…]

Table 1

Undesirable effects in clinical studies and from post-marketing experience

[…]

Metabolism and nutrition disorders	Uncommon: Dyslipidaemia

[…]