J-C Health Care Ltd.

Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

02.2025

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון: Remicade - רמיקד

חברת J-C Health Care Ltd מבקשת להודיעכם כי העלונים לרופא ולצרכן של התכשיר שבנדון התעדנו **בפברואר 2025.**

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן באדום, טקסט שהושמט מסומן בטקסט ~~בחול עם קו חוצה~~, טקסט המהווה החמרה מודגש ברקע צהוב),אך קיימים עדכונים נוספים.

ההתוויות המאושרות לתכשיר בישראל:

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 convential 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

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מרכיב פעיל: Infliximab

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

כמו כן, מצורפים לפרסום זה וניתן לקבל העתק מודפס שלהם באמצעות פנייה לבעל הרישום: J-C Health Care Ltd, קיבוץ שפיים, 6099000, טל': 09-9591111.

בברכה,

יעל לפידות מללי
רוקחת ממונה
J-C Health Care Ltd

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העדכון בעלון לרופא הינו:

4.4 Special warnings and precautions for use

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Others
~~There is limited safety experience of Remicade 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 Remicade should be closely monitored for infectio~~n~~us and non-infectious complications, and appropriate actions should be taken (see section 4.8).

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4.8 Undesirable effects

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Table 1
Undesirable effects in clinical studies and from post-marketing experience

Infections and infestations		
	Very Common:	Viral infection (e.g. influenza, herpes virus infection).
	Common:	Bacterial infections (e.g. sepsis, cellulitis, abscess).
	Uncommon:	Tuberculosis, fungal infections (e.g. candidiasis, onychomycosis,).
	Rare:	Meningitis, opportunistic infections (such as invasive fungal infections [pneumocystosis, histoplasmosis, aspergillosis, coccidioidomycosis, cryptococcosis, blastomycosis], bacterial infections [atypical mycobacterial, listeriosis, salmonellosis], and viral infections [cytomegalovirus]), parasitic infections, hepatitis B reactivation.
	Not known	Vaccine breakthrough infection (after *in utero* exposure to infliximab)*.
Neoplasms benign, malignant and unspecified (including cysts and polyps)		
	Rare:	Lymphoma, non-Hodgkin's lymphoma, Hodgkin's disease, leukaemia, melanoma, cervical cancer
	Not known:	Hepatosplenic T-cell lymphoma (primarily in adolescents and young adult males with Crohn's disease or ulcerative colitis) , Merkel cell carcinoma, Kaposi's sarcoma.
Blood and lymphatic system disorders		
	Common:	Neutropenia, leucopenia, anaemia, lymphadenopathy.
	Uncommon:	Thrombocytopenia, lymphopenia, lymphocytosis.
	Rare:	Agranulocytosis (including infants exposed *in utero* to infliximab), thrombotic thrombocytopenic purpura, pancytopenia, haemolytic anaemia, idiopathic thrombocytopenic purpura.
Immune system disorders		
	Common:	Allergic respiratory symptom.
	Uncommon:	Anaphylactic reaction, lupus-like syndrome, serum sickness or serum sickness-like reaction.
	Rare:	Anaphylactic shock, vasculitis, sarcoid-like reaction.

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Metabolism and nutrition disorders	
Uncommon:	Dyslipidaemia
Psychiatric disorders	
Common:	Depression, insomnia.
Uncommon:	Amnesia, agitation, confusion, somnolence, nervousness.
Rare:	Apathy.
Nervous system disorders	
Very common:	Headache.
Common:	Vertigo, dizziness, hypoaesthesia, paraesthesia.
Uncommon:	Seizure, neuropathy.
Rare:	Transverse myelitis, central nervous system demyelinating disorders (multiple sclerosis-like disease and optic neuritis), peripheral demyelinating disorders (such as Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy and multifocal motor neuropathy).
Not known:	Cerebrovascular accidents in close temporal association with infusion.
Eye disorders	
Common:	Conjunctivitis.
Uncommon:	Keratitis, periorbital oedema, hordeolum.
Rare:	Endophthalmitis.
Not known	Transient visual loss occurring during or within 2 hours of infusion.
Cardiac disorders	
Common:	Tachycardia, palpitation.
Uncommon:	Cardiac failure (new onset or worsening), arrhythmia, syncope, bradycardia.
Rare:	Cyanosis, pericardial effusion.
Not known:	Myocardial ischaemia/myocardial infarction
Vascular disorders	
Common:	Hypotension, hypertension, ecchymosis, hot flush, flushing.
Uncommon:	Peripheral ischaemia, thrombophlebitis, haematoma.
Rare:	Circulatory failure, petechia, vasospasm.
Respiratory, thoracic and mediastinal disorders	
Very common:	Upper respiratory tract infection, sinusitis.
Common:	Lower respiratory tract infection (e.g. bronchitis, pneumonia), dyspnoea, epistaxis.
Uncommon:	Pulmonary oedema, bronchospasm, pleurisy, pleural effusion.
Rare:	Interstitial lung disease (including rapidly progressive disease, lung fibrosis and pneumonitis).
Gastrointestinal disorders	
Very common:	Abdominal pain, nausea.
Common:	Gastrointestinal haemorrhage, diarrhoea, dyspepsia, gastroesophageal reflux, constipation.
Uncommon:	Intestinal perforation, intestinal stenosis, diverticulitis, pancreatitis, cheilitis.
Hepatobiliary disorders	
Common:	Hepatic function abnormal, transaminases increased.
Uncommon:	Hepatitis, hepatocellular damage, cholecystitis.
Rare:	Autoimmune hepatitis, jaundice.
Not known:	Liver failure.
Skin and subcutaneous tissue disorders	
Common:	New onset or worsening psoriasis including pustular psoriasis (primarily palm & soles), urticaria, rash, pruritus, hyperhidrosis, dry skin, fungal dermatitis, eczema, alopecia.

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Uncommon:	Bullous eruption, seborrhoea, rosacea, skin papilloma, hyperkeratosis, abnormal skin pigmentation.
Rare:	Toxic epidermal necrolysis, Stevens-Johnson Syndrome, erythema multiforme, furunculosis, linear IgA bullous dermatosis (LABD), acute generalised exanthematous pustulosis (AGEP), lichenoid reactions. worsening of symptoms of dermatomyositis
Not known:	
Musculoskeletal and connective tissue disorders	
Common:	Arthralgia, myalgia, back pain.
Renal and urinary disorders	
Common:	Urinary tract infection.
Uncommon:	Pyelonephritis.
Reproductive system and breast disorders	
Uncommon:	Vaginitis.
General disorders and administration site conditions	
Very common:	Infusion-related reaction, pain.
Common:	Chest pain, fatigue, fever, injection site reaction, chills, oedema.
Uncommon:	Impaired healing.
Rare:	Granulomatous lesion.
Investigations	
Uncommon:	Autoantibody positive, weight increased[1].
Rare:	Complement factor abnormal.
Injury, poisoning, and procedural complications	
Not known:	Post-procedural complication (including infectious and non-infectious complications)

* 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.

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העדכון בעלון לצרכן הינו:

4. תופעות לוואי

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

- סרטן בילדים ובמבוגרים
- סרטן דם נדיר המופיע בעיקר אצל נערים בגיל העשרה או גברים צעירים (Hepatosplenic) T-cell lymphoma
- אי ספיקת כבד
- קרצינומה של תאי מרקל (סוג של סרטן עור)
- סרקומה על שם קפושי (Kaposi's sarcoma), סרטן נדיר הקשור לזיהום בנגיף ההרפס הומני 8 (human herpes virus 8). סרקומה על שם קפושי מופיעה לרוב כנגעים סגולים על העור.
- החמרה של מצב הנקרא דלקת עור ושרירים Dermatomyositis (נראה כפריחה בעור המלווה בחולשת שרירים)
- התקף לב
- שבץ
- אובדן ראייה זמני במהלך או תוך שעתיים מהעירוי
- זיהום כתוצאה מחיסון חי בגלל מערכת חיסונית מוחלשת
- בעיות בעקבות הליך רפואי (כולל בעיות זיהומיות ולא זיהומיות)

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