J-C Health Care Ltd.

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פבר' 2021

רופא/ה נכבד/ה
רוקח/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 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

השינויים המהותיים בעלון <u>לרופא</u> מופיעים בסעיפים הבאים:

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4.8 Undesirable effects

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.

השינויים המהותיים בעלון לצרכן מופיעים בסעיפים הבאים:

4. תופעות לוואי

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תופעות לוואי ששכיחותן אינה ידועה (תופעות ששכיחותן טרם נקבעה)

סרטן בילדים ובמבוגרים

סרטן דם נדיר המופיע בעיקר בנערים בני עשרה או בגברים צעירים (Hepatosplenic T-cell lymphoma)

כשל כבדי

Merkel cell carcinoma (סוג של סרטן עור)

סרקומה ע"ש קפושי (Kaposi's sarcoma), סוג סרטן נדיר הקשור לזיהום בנגיף ההרפס האנושי 8 (human herpes virus 8). סרקומה ע"ש קפושי מתבטאת בעיקר בנגעים סגולים על גבי העור.

החמרה של מצב הנקרא דלקת עור ושרירים Dermatomyositis (נראה כפריחה בעור המלווה בחולשת שרירים)

התקף לב

שבץ

אובדן ראייה זמני במשך או תוך שעתיים מהעירוי

זיהום כתוצאה מחיסון חי בשל מערכת חיסונית מוחלשת

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Instructions for use and handling – reconstitution, dilution and administration

1. Calculate the dose and the number of Remicade vials needed. Each Remicade vial contains 100 mg infliximab. Calculate the total volume of reconstituted Remicade solution required.

2. Under aseptic conditions, reconstitute each Remicade vial with 10 ml of water for injections, using a syringe equipped with a 21-gauge (0.8 mm) or smaller needle. Remove flip-top from the vial and wipe the top with a 70% alcohol swab. Insert the syringe needle into the vial through the centre of the rubber stopper and direct the stream of water for injections to the glass wall of the vial. Gently swirl the solution by rotating the vial to dissolve the lyophilised powder. Avoid prolonged or vigorous agitation. DO NOT SHAKE. Foaming of the solution on reconstitution is not unusual. Allow the reconstituted solution to stand for 5 minutes. Check that the solution is colourless to light yellow and opalescent. The solution may develop a few fine translucent particles, as infliximab is a protein. Do not use if opaque particles, discolouration, or other foreign particles are present.

3. Dilute the total volume of the reconstituted Remicade solution dose to 250 ml with sodium chloride 9 mg/ml (0.9%) solution for infusion. Do not dilute the reconstituted Remicade solution with any other diluent. The dilution can be accomplished by withdrawing a volume of the sodium chloride 9 mg/ml (0.9%) solution for infusion from the 250-ml glass bottle or infusion bag equal to the volume of reconstituted Remicade. Slowly add the total volume of reconstituted Remicade solution to the 250-ml infusion bottle or bag. Gently mix. For volumes greater than 250 ml, either use a larger infusion bag (e.g. 500 ml, 1000 ml) or use multiple 250 ml infusion bags to ensure that the concentration of the infusion solution does not exceed 4 mg/ml. If stored refrigerated after reconstitution and dilution, the infusion solution must be allowed to equilibrate at room temperature to 25-°C for 3 hours prior to Step 4 (infusion).

4. Administer the infusion solution over a period of not less than the infusion time recommended. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 1.2 micrometre or less). Since no preservative is present, it is recommended that the administration of the solution for infusion is to be started as soon as possible and within 3 hours of reconstitution and dilution. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-°C--8-°C, unless reconstitution/dilution has been taken place in controlled and validated aseptic conditions. Do not store any unused portion of the infusion solution for reuse.

5. No physical biochemical compatibility studies have been conducted to evaluate the co-administration of Remicade with other agents. Do not infuse Remicade concomitantly in the same intravenous line with other agents.

6. Visually inspect Remicade for particulate matter or discolouration prior to administration. Do not use if visibly opaque particles, discolouration or foreign particles are observed.

7. Any unused product or waste material should be disposed of in accordance with local requirements.

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