נספח 1:

הודעה על חזרה לשיווק של תכשיר REMSIMA 100 MG I.V.

תאריך ההודעה: **26/06/2024**

בעל הרישום **פאדאגיס ישראל סוכנויות בע"מ** מודיע על **חזרה לשיווק** של התכשיר **REMSIMA 100 MG I.V.**:

מספר רישום	154 60 34158 00
שם התכשיר בעברית	רמסימה 100 מ"ג תוך-ורידי
שם התכשיר באנגלית	REMSIMA 100 MG I.V.
צורת מינון	אבקה להכנת תמיסה מרוכזת לעירוי
דרך מתן	תוך-ורידי
מרכיב פעיל	INFLIXIMAB
חוזק	100 MG/VIAL
התוויה	* **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. *** <u>Psoriasis:</u>** 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) *** <u>Adult 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>Paediatric Crohn's disease</u>** 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.	
17/06/2024	תאריך תחילת הפסקת השיווק
07/07/2024	תאריך צפי לסיום הפסקת השיווק (במידה ומדובר בהארכה יש לרשום "XXXX/XX/XX במקום XXXX/XX/XX" (תאריך הצפי האחרון)
26/06/2024	תאריך חזרה לשיווק (יש למלא משבצת זאת **עם** חזרת התכשיר לשיווק **בפועל**)
כן	הכללה בסל הבריאות: כן / לא
סיבות תפעוליות	סיבת הפסקת השיווק: סיבות תפעוליות / סיבות מסחריות
1 VIAL	גודל/י אריזה (נא לרשום את כל הגדלים הרלוונטיים להודעה זאת)
NA	זמינות של גודל אריזה אחר או חוזק אחר של התכשיר