נספח 1:

הודעה על חזרה לשיווק

תאריך ההודעה: 08.03.2026

בעל הרישום ניאופרם בע"מ מודיע על **חזרה לשיווק** של:

מספר רישום	152-53-33883-00
שם התכשיר בעברית	**סימזיה**
שם התכשיר באנגלית	**Cimzia®**
צורת מינון	Solution for injection
דרך מתן	S.C.
מרכיב פעיל	certolizumab pegol
חוזק	200 mg/ml
התוויה	Rheumatoid arthritis: Cimzia, in combination with methotrexate (MTX), is indicated for: the treatment of moderate to severe, active rheumatoid arthritis (RA) in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including methotrexate, has been inadequate. Cimzia can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Cimzia has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate. Axial spondyloarthritis: Cimzia is indicated for the treatment of adult patients with severe active axial spondyloarthritis, comprising: Ankylosing spondylitis (AS): Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). Axial spondyloarthritis without radiographic evidence of AS Adults with severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated C reactive protein (CRP) and /or magnetic resonance imaging (MRI), who have had an inadequate response to, or are intolerant to NSAIDs.

	Crohn's Disease: CIMZIA is indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. Plaque psoriasis: Cimzia is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
תאריך תחילת הפסקת השיווק	10.03.2026
תאריך צפי לסיום הפסקת השיווק	31.03.2026
תאריך חזרה לשיווק (יש למלא משבצת זאת עם חזרת התכשיר לשיווק **בפועל**)	**08.03.2026**
הכללה בסל הבריאות : כן / לא	כן
סיבת הפסקת השיווק : סיבות תפעוליות / סיבות מסחריות	סיבות תפעוליות
גודל/י אריזה	2 pre-filled syringes
זמינות של גודל אריזה אחר או חוזק אחר של התכשיר	אין