

10-2022

## Cimzia

(Certolizumab pegol 200 mg/ml)

solution for injection in prefilled syringe

S.C

רופא/ה, רוקח/ת נכבד/ה,

- אנו מתכבדים להודיעך על עדכון בעלון לרופא עבור התכשיר בנדון.
- העדכון מובא בהודעה זו: טקסט חדש מופיע בכחול, טקסט שהוסר מופיע באדום עם קו-חוצה.

### להלן נוסח ההתוויה המאושר לתכשיר:

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.

### העדכון בעלון לרופא נעשה בסעיף הבא:

#### 4.6 Fertility, pregnancy and lactation

##### Pregnancy

Data from more than ~~500~~ 1300 prospectively collected pregnancies exposed to Cimzia with known pregnancy outcomes, including more than ~~400~~ 1000 pregnancies exposed during the first trimester, does not indicate a malformative effect of Cimzia. [Further data](#)

are being collected as the available clinical experience is still ~~too~~-limited to ~~\_, with a~~  
~~reasonable certainty~~ conclude that there is no increased risk associated with Cimzia  
administration during pregnancy.

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- העלון לרופא נשלח למשרד הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד הבריאות.
- ניתן לקבל עלון זה מודפס על ידי פניה ישירה לבעל הרישום:  
ניאופרם בע"מ, רח' השילוח 6, ת.ד. 7063, פתח תקווה 4917001, טלפון: 03-9373737.

בברכה,

עוז וולך  
רוקח ממונה

ניאופרם בע"מ