14.04.2022

Cimzia

(Certolizumab pegol 200 mg/ml)

solution for injection in prefilled syringe

רופא/ה, רוקח/ת נכבד/ה,

- **אנו מתכבדים להודיעך על עדכון בעלון לרופא עבור התכשיר בנדון.**
- העדכון מובא בהודעה זו, טקסט שנוסף לעלון מופיע על רקע צהוב.

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:

4.8 Undesirable effects

Summary of the safety profile
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Axial spondyloarthritis

Cimzia was studied in 325 patients with active axial spondyloarthritis (including ankylosing spondylitis and non-radiopraphic axial spondyloarthritis) in the AS001 clinical study for up to 4 years, which includes a 24-week placebo-controlled phase followed by a 24-week dose-blind period and a 156-week open-label treatment period. Cimzia was also studied in 317

patients with non-radiographic axial spondyloarthritis in a placebo-controlled study for 52 weeks (AS0006). Cimzia was also studied in a 96-week open-label study in 89 axSpA patients with a history of documented anterior uveitis flares. In ~~both~~ all three studies~~.~~ , The safety profile for these patients was consistent with the safety profile in rheumatoid arthritis and previous experience with Cimzia.
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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,

אבי ילצינדג
רוקח ממונה
ניאופרם בע"מ