יוני 2025

Cimzia®
סימזיה®

מרכיב פעיל: certolizumab pegol 200 mg / 1 ml
צורת מינון: solution for injection

רופא/ה, רוקח/ת נכבד/ה,
חברת ניאופרם בע"מ מבקשת להודיע על עדכון העלון לרופא והעלון לצרכן של התכשיר שבנדון.
העלונים עודכנו בתאריך יוני 2025.

ההתוויות הרשומות לתכשיר בישראל:

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) (also known as radiographic axial spondyloarthritis)
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 (also known as non-radiographic axial spondyloarthritis)
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.

Plaque psoriasis
Cimzia is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

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.

ניאופרם (ישראל) 1996 בע"מ בנין ניאופרם, רח' השילוח 6 ת.ד. 7063 פתח תקוה 4917001
Email: neopharm@neopharmisrael.com פקס: 03-9373716 טל: 03-9373737 www.neopharmgroup.com

מקרא לעדכונים המסומנים:
מידע שהוסר - מסומן ~~בקו אדום חוצה~~
תוספת -כתב **כחול**
תוספת החמרה - כתב **כחול - מסומן במרקר צהוב**

עדכונים מהותיים נעשו בסעיף הבא בעלון לצרכן:

2. לפני השימוש בתרופה:
...
הריון, הנקה ופוריות
...
~~קיים ניסיון מוגבל בשימוש בסימזיה בנשים הרות~~. השימוש בסימזיה במהלך הריון ניתן רק אם קיים צורך חד משמעי. אם את אישה בפוטנציאל פוריות, דברי עם הרופא שלך בנוגע לשימוש באמצעי מניעה יעילים בתקופת השימוש בסימזיה. לנשים אשר מתכננות להיכנס להריון, ניתן לשקול שימוש באמצעי מניעה במהלך 5 חודשים לאחר המנה האחרונה של סימזיה.
...

עדכונים מהותיים נעשו בסעיף הבא בעלון לרופא:

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4.6 Fertility, pregnancy and lactation

Women of childbearing potential

The use of adequate contraception should be considered for women of childbearing potential. For women planning pregnancy, the clinical need for ongoing Cimzia treatment should be evaluated. If the decision is made to clear Cimzia from the body prior to conception, contraception should be continued ~~contraception may be considered~~ for 5 months after the last Cimzia dose ~~due to its elimination rate~~ (see section 5.2)~~, but the need for treatment of the woman should also be taken into account (see below)~~.

Pregnancy

~~Data from more than 1300 prospectively collected pregnancies exposed to Cimzia with known pregnancy outcomes, including more than 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 limited to conclude that there is no increased risk associated with Cimzia administration during pregnancy.~~

~~Animal studies using a rodent anti-rat TNFα did not reveal evidence of impaired fertility or harm to the foetus. However, these are insufficient with respect to human reproductive toxicity (see section 5.3). Due to its inhibition of TNFα, Cimzia administered during pregnancy could affect normal immune response in the newborn.~~

~~Cimzia should only be used during pregnancy if clinically needed.~~

~~Non-clinical studies suggest low or negligible level of placental transfer of a homologue Fab-fragment of certolizumab pegol (no Fc region) (see section 5.3).~~

Human data

A large amount of data (more than 1500 pregnancies exposed to Cimzia during the first trimester) from prospectively reported pregnancies with known pregnancy outcomes, indicate no malformative nor feto/neonatal toxicity. Continuous data collection is ongoing with pharmacovigilance cases reporting and a pregnancy registry.

In a pregnancy register (the OTIS study) the proportion of major birth defects in live-born infants was 15/132 (11.4%) in women treated with Cimzia at least during the first trimester, and 8/126 (6.3%) in women with the same indicated diseases but not treated with Cimzia (relative risk 1.85; 95% CI 0.74 to 4.60). A similar association was seen when women treated with Cimzia were compared with women not having a disease consistent with approved Cimzia indications (proportion 10/126 [7.9%] and relative risk 1.65; 95% CI 0.75 to 3.64). No pattern of major or minor defects was identified.

There were no distinct differences between the Cimzia treated group and both comparison groups for spontaneous abortion, serious or opportunistic infections, hospitalization, adverse vaccine reactions, in the children who were followed up for up to 5 years of age. No stillbirths or termination were reported in the Cimzia arm while 2 stillbirths and 3 pregnancy terminations were reported in the disease unexposed arm. The interpretation of data may be impacted due to methodological limitations of the study, including small sample size and non-randomized design.

In a clinical study of 21 women receiving Cimzia during pregnancy, certolizumab pegol plasma concentrations were within the range of concentrations observed in non-pregnant adult patients (see section 5.2).

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Animal data

Animal studies using a rodent anti-rat TNFα did not reveal evidence of impaired fertility or harm to the foetus. However, these are insufficient with respect to human reproductive toxicity (see section 5.3). Due to its inhibition of TNFα, Cimzia administered during pregnancy could affect normal immune response in the newborn.

Non-clinical studies suggest low or negligible level of placental transfer of a homologue Fab-fragment of certolizumab pegol (no Fc region) (see section 5.3).

Cimzia should only be used during pregnancy if clinically needed. No dose adjustment is needed.

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5.2 Pharmacokinetic properties

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Pregnancy

In a clinical study, 21 women received Cimzia at a maintenance dose of 200 mg or 400 mg every 2 weeks or 400 mg every 4 weeks, during pregnancy and at least 13 weeks post-partum (see section 4.6).

Based on population PK modeling, median systemic Cimzia exposure for the dosing regimens studied were estimated to be 22% (AUC) and 36% (Cmin) lower during pregnancy (with the greatest reduction observed during the third trimester) relative to post-partum or in non-pregnant individuals.

Although certolizumab pegol plasma concentrations were lower during pregnancy compared with post-partum, they were still within the range of concentrations observed in non-pregnant adult patients with psoriasis, axSpA, and rheumatoid arthritis.

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קיימים עדכונים נוספים. למידע נוסף יש לעיין בעלון לרופא ובעלון לצרכן המעודכנים.

העלון לרופא והעלון לצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום ניאופרם בע"מ, בנין ניאופרם, רח' השילוח 6 ת.ד. 7063 פתח-תקוה 4917001, טלפון: 03-9373737, פקס: 03-9373770

בברכה,

אבי ילצינדג
רוקח ממונה