ספטמבר 2024

Bimzelx®
בימזלקס®

מרכיב פעיל: bimekizumab 160 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 ספטמבר 2024.

ההתוויות הרשומות לתכשיר בישראל:

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

Psoriatic arthritis
Bimzelx, alone or in combination with a conventional non-biologic disease-modifying antirheumatic drug (cDMARD) (e.g., methotrexate), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).

Axial spondyloarthritis

Non-radiographic axial spondyloarthritis (nr-axSpA)

Bimzelx is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).

Ankylosing spondylitis (AS, radiographic axial spondyloarthritis)

Bimzelx is indicated for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.

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

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עדכונים מהותיים נעשו בסעיף הבא בעלון לצרכן:

1. למה מיועדת התרופה?

בימזלקס מיועד לטיפול במחלות הדלקתיות הבאות:

- בספחת (פסוריאזיס) רובדית בינונית עד חמורה, במבוגרים שמועמדים לטיפול סיסטמי
- דלקת מפרקים ספחתית (Psoriatic arthritis) פעילה כטיפול יחיד או בשילוב עם תרופות מסוג cDMARDs (למשל, מתוטרקסט), במבוגרים שהגיבו בצורה לא מספקת או שחוו אי-סבילות לאחת או יותר מתרופות מסוג DMARDs
- דלקת חוליות מקשחת (Ankylosing spondylitis) פעילה, במבוגרים אשר חוו תגובה לא מספקת או אי-סבילות לטיפול מקובל
- דלקת חוליות מקשחת ללא עדות רדיוגרפית (Non-radiographic axial spondyloarthritis) פעילה, במבוגרים עם סימני דלקת המובחנים על ידי עלייה ברמות חלבון CRP ו/או על ידי MRI, אשר חוו תגובה לא מספקת או אי-סבילות לתרופות מסוג נוגדי דלקת שאינם סטרואידיים (NSAIDs)

קבוצה תרפויטית: מדכאי מערכת חיסון, מעכבי אינטרלוקין.
בימקיזומאב פועל על ידי הפחתת פעילות שני חלבונים הנקראים IL-17A ו-IL-17F, המעורבים ביצירת דלקת. קיימות רמות גבוהות יותר של חלבונים אלה במחלות דלקתיות כמו פסוריאזיס, דלקת מפרקים ספחתית ודלקת חוליות מקשחת.

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3. כיצד תשתמש בתרופה?

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ספחת (פסוריאזיס) רובדית

- 320 מ"ג (ניתן באמצעות **שני** עטים מוכנים להזרקה, המכילים 160 מ"ג כל אחד) בשבועות 0, 4, 8, 12, 16.
- משבוע 16, תשתמש ב-320 מ"ג (**שני** עטים מוכנים להזרקה, המכילים 160 מ"ג כל אחד) כל 8 שבועות. אם אתה שוקל מעל ל-120 ק"ג, הרופא שלך עשוי להחליט להמשיך במתן זריקות כל 4 שבועות.

דלקת מפרקים ספחתית (Psoriatic arthritis)

- 160 מ"ג (ניתן באמצעות עט **אחד** מוכן להזרקה) כל 4 שבועות.
- אם אובחנת בדלקת מפרקים ספחתית יחד עם ספחת רובדית בינונית עד חמורה, המינון המומלץ זהה לזה הניתן לטיפול בספחת. לאחר השבוע ה-16, הרופא שלך עשוי לשנות את המינון עבורך ל-160 מ"ג כל 4 שבועות, כתלות בתסמיני המפרקים שלך.

דלקת חוליות מקשחת (Ankylosing spondylitis) ודלקת חוליות מקשחת ללא עדות רדיוגרפית (Non-radiographic axial spondyloarthritis)

- 160 מ"ג (ניתן באמצעות עט **אחד** מוכן להזרקה) כל 4 שבועות.

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עדכונים מהותיים נעשו בסעיף הבא בעלון לרופא:

4.1 Therapeutic indications

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Plaque psoriasis

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

Psoriatic arthritis

Bimzelx, alone or in combination with a conventional non-biologic disease-modifying antirheumatic drug (cDMARD) (e.g., methotrexate), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).

Axial spondyloarthritis

Non-radiographic axial spondyloarthritis (nr-axSpA)

Bimzelx is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).

Ankylosing spondylitis (AS, radiographic axial spondyloarthritis)

Bimzelx is indicated for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.

4.2 Posology and method of administration

Bimzelx is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which Bimzelx is indicated ~~plaque psoriasis~~.

Posology

Plaque psoriasis

The recommended dose for adult patients with plaque psoriasis is 320 mg (given as 2 subcutaneous injections of 160 mg each) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter.

Psoriatic arthritis

The recommended dose for adult patients with active psoriatic arthritis is 160 mg (given as 1 subcutaneous injection of 160 mg) every 4 weeks.
For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, the recommended dose is the same as for plaque psoriasis [320 mg (given as 2 subcutaneous injections of 160 mg each) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter]. After 16 weeks, regular assessment of efficacy is recommended and if a sufficient clinical response in joints cannot be maintained, a switch to 160 mg every 4 weeks can be considered.

Axial spondyloarthritis (nr-axSpA and AS)

The recommended dose for adult patients with axial spondyloarthritis is 160 mg (given as 1 subcutaneous injection) every 4 weeks.

For above indications, consideration should be given to discontinuing treatment in patients who have shown no improvement by 16 weeks of treatment.

Special populations

Overweight patients with plaque psoriasis

For some patients with plaque psoriasis (including psoriatic arthritis with coexistent moderate to severe psoriasis) and a body weight ≥ 120 kg who did not achieve complete skin clearance at week 16, 320 mg every 4 weeks after week 16 may further improve treatment response (see section 5.1).

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4.5 Interaction with other medicinal products and other forms of interaction

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Population pharmacokinetic (PK) data analyses indicated that concomitant administration of conventional disease modifying antirheumatic drugs (cDMARDs) including methotrexate or prior exposure to biologics have no clinically relevant impact on the clearance of bimekizumab.

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4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions were upper respiratory tract infections (14.5%, 14.6%, 16.3% in plaque psoriasis, psoriatic arthritis and axial spondyloarthritis (axSpA) respectively) and oral candidiasis (7.3%, 2.3%, 3.7% in PSO, PsA and axSpA respectively).

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Table 1: List of adverse reactions

System Organ Class	Frequency	Adverse reaction
…	…	…
General disorders and administration site conditions	Common	Injection site reactions[a], Fatigue
[a)] Includes: injection site erythema, reaction, oedema, pain, swelling, haematoma.		

Description of selected adverse reactions

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Infection rates observed in PsA and axSpA (nr-axSpA and AS) Phase III clinical studies were similar to those observed in plaque psoriasis apart from oral and oropharyngeal candidiasis rates in patients treated with bimekizumab, which were lower at 2.3% and 0% respectively in PsA and 3.7% and 0.3% respectively in axSpA compared to 0% with placebo.

Neutropenia

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The frequency of neutropenia in PsA, axSpA (nr-axSpA and AS) clinical studies was similar to that observed in plaque psoriasis studies.

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Immunogenicity

Plaque psoriasis

Approximately 45% of plaque psoriasis patients treated with bimekizumab up to 56 weeks at the recommended dosing regimen (320 mg every 4 weeks up to week 16 and 320 mg every 8 weeks thereafter) developed anti-drug antibodies. Of the patients who developed anti-drug antibodies, approximately 34% (16% of all patients treated with bimekizumab) had antibodies that were classified as neutralising. ~~No evidence of altered clinical response, or significantly altered safety profile was associated with anti bimekizumab antibodies development.~~

Psoriatic arthritis

Approximately 31% of patients with psoriatic arthritis treated with bimekizumab at the recommended dosing regimen (160 mg every 4 weeks) up to 16 weeks had anti-drug antibodies. Of the patients with anti-drug antibodies, about 33% (10% of all patients treated with bimekizumab) had antibodies that were classified as neutralising. By week 52, approximately 47% of biologic disease-modifying anti-rheumatic drug (bDMARD) treatment naïve patients with psoriatic arthritis in the BE OPTIMAL study treated with bimekizumab at the recommended dosing regimen (160 mg every 4 weeks) had anti-drug antibodies. Of the patients with anti-drug antibodies, about 38% (18% of all patients in the BE OPTIMAL study treated with bimekizumab) had antibodies that were classified as neutralising.

Axial spondyloarthritis (nr-axSpA and AS)

Approximately 57% of patients with nr-axSpA treated with bimekizumab up to 52 weeks at the recommended dosing regimen (160 mg every 4 weeks) had anti-drug antibodies. Of the patients with anti-drug antibodies, approximately 44% (25% of all patients treated with bimekizumab) had antibodies that were classified as neutralising.

Approximately 44% of patients with AS treated with bimekizumab up to 52 weeks at the recommended dosing regimen (160 mg every 4 weeks) had anti-drug antibodies. Of the patients with anti-drug antibodies, approximately 44% (20% of all patients treated with bimekizumab) had antibodies that were classified as neutralising.

Across indications, no clinically meaningful impact on clinical response was associated with anti-bimekizumab antibodies development and an association between immunogenicity and treatment emergent adverse events has not been clearly established.

Elderly patients (≥65 years)

Exposure is limited in elderly subjects.

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In the placebo-controlled period of Phase III clinical studies in psoriatic arthritis, oral candidiasis was observed in 7.0% of patients ≥65 years versus 1.6% in <65 years, dermatitis and eczema in 1.2% of patients ≥65 years versus 2.0% in <65 years.

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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,

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