מאי 2025

DUPIXENT 300mg solution for injection

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חומר פעיל: dupilumab 300mg/2ml (150 mg/ml)

חומר פעיל: dupilumab 200mg/1.14ml (175 mg/ml)

ההתוויות המאושרות:

Atopic Dermatitis

DUPIXENT is indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.

Asthma

DUPIXENT is indicated as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.

Limitation of Use

DUPIXENT is not indicated for the relief of acute bronchospasm or status asthmaticus.

Chronic Rhinosinusitis with Nasal Polyposis

DUPIXENT 300mg is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

Eosinophilic Esophagitis

DUPIXENT is indicated for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).

Prurigo Nodularis

DUPIXENT 300mg is indicated for the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy.

Chronic Obstructive Pulmonary Disease

DUPIXENT is indicated as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

Limitations of Use:

DUPIXENT is not indicated for the relief of acute bronchospasm.

חברת סאנופי מבקשת להודיע על עדכון העלונים לרופא ולצרכן.

העדכונים העיקריים הינם:

בעלון לרופא:

5 WARNINGS AND PRECAUTIONS

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5.3 Eosinophilic Conditions

Patients being treated for asthma may present with ~~serious systemic eosinophilia sometimes presenting with~~ clinical features of eosinophilic pneumonia or ~~vasculitis consistent with~~ eosinophilic granulomatosis with polyangiitis~~, conditions which are often treated with systemic corticosteroid therapy~~ (EGPA). These events may be associated with the reduction of oral corticosteroid therapy. Healthcare providers should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, kidney injury, and/or neuropathy presenting in their patients with eosinophilia. Cases of eosinophilic pneumonia were reported in adults ~~subjects~~ who participated in the asthma development program. ~~and c~~Cases of ~~vasculitis consistent with eosinophilic granulomatosis with polyangiitis~~ EGPA have been reported with DUPIXENT in adults ~~subjects~~ who participated in the asthma development program as well as in adults ~~subjects~~ with co-morbid asthma in the CRSwNP development program. ~~A causal association between~~Advise patients to report signs of eosinophilic pneumonia and EGPA to their healthcare provider. Consider withholding DUPIXENT ~~and these conditions has not been established~~ if eosinophilic pneumonia or EGPA are suspected.

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5.7 Psoriasis

Cases of new-onset psoriasis have been reported with the use of DUPIXENT for the treatment of atopic dermatitis and asthma, including in patients without a family history of psoriasis. In postmarketing reports, onset of psoriasis varied from weeks to months after the first dose of DUPIXENT and resulted in partial or complete resolution of psoriasis with discontinuation of dupilumab, with or without use of supplemental treatment for psoriasis (topical or systemic). Those who continued on dupilumab received supplemental treatment for psoriasis to improve associated symptoms. Advise patients to

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report new-onset psoriasis symptoms to their healthcare provider. If symptoms persist or worsen, consider dermatologic evaluation and/or discontinuation of DUPIXENT.

5.~~7~~8 Arthralgia and Psoriatic Arthritis

Arthralgia has been reported with the use of DUPIXENT with some patients reporting gait disturbances or decreased mobility associated with joint symptoms; some cases resulted in hospitalization *[see Adverse Reactions (6.1)]*. In postmarketing reports, onset of arthralgia was variable, ranging from days to months after the first dose of DUPIXENT.

Cases of new-onset psoriatic arthritis requiring systemic treatment have been reported with the use of DUPIXENT.

-Some patients' symptoms resolved while continuing treatment with DUPIXENT, and other patients recovered or were recovering following discontinuation of DUPIXENT. Advise patients to report new onset or worsening joint symptoms to their healthcare provider. If symptoms persist or worsen, consider rheumatological evaluation and/or discontinuation of DUPIXENT.

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6. ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Hypersensitivity *[see Warnings and Precautions (5.1)]*
- Conjunctivitis and Keratitis *[see Warnings and Precautions (5.2)]*
- Psoriasis *[see Warnings and Precautions (5.7)]*
- Arthralgia and Psoriatic Arthritis *[see Warnings and Precautions (5.~~7~~8)]*
- Parasitic (Helminth) Infections *[see Warnings and Precautions (5.~~8~~9)]*

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6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of DUPIXENT. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- *Immune system disorders:* angioedema ~~*[see Warnings and Precautions (5.1)]*~~
- *Musculoskeletal system disorders:* psoriatic arthritis
- *Skin and subcutaneous tissue disorders:* Facial skin reactions, including erythema, rash, scaling, edema, papules, pruritus, burning, and pain; new-onset psoriasis, vasculitis.

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CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by specifically binding to the IL-4Rα subunit shared by the IL-4 and IL-13 receptor complexes. Dupilumab inhibits IL-4 signaling via the Type I receptor and both IL-4 and IL-13 signaling through the Type II receptor.

Inflammation driven by IL-4 and IL-13 is an important component in the pathogenesis of asthma, AD, CRSwNP, EoE, PN and COPD. Multiple cell types that express IL-4Rα (e.g., mast cells, basophils, eosinophils, macrophages, lymphocytes, epithelial cells, goblet cells) and inflammatory mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines, chemokines) are involved in inflammation. Blocking IL-4Rα with dupilumab inhibits IL-4 and IL-13 cytokine-induced inflammatory responses, including the release of proinflammatory cytokines, chemokines, nitric oxide, and IgE. The mechanism of dupilumab action has not been definitively established.

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בעלונים לצרכן (עבור שני המינונים, באריזת מזרקים ובאריזת עטי הזרקה):

4. תופעות לוואי

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דופיקסנט יכולה לגרום לתופעות לוואי חמורות כולל:

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- **דלקת בכלי הדם.** לעיתים נדירות חולים הסובלים מאסתמה עלולים לפתח תופעה זו. זה קורה אצל אנשים שנוטלים גם תרופה ממשפחת הסטרואידים דרך הפה אך מפסיקים את הטיפול בה או שהמינון שלה מופחת. ~~לא ידוע אם הדבר נגרם על ידי דופיקסנט.~~ספר לרופא מייד אם יש לך: פריחה, כאב בחזה, החמרה בקוצר נשימה, שתן בצבע חום או בצבע כהה, הרגשה של דקירות/סיכות או אובדן תחושה בזרועות או ברגליים, חום מתמשך.
- **פסוריאזיס.** זה יכול לקרות אצל אנשים עם אטופיק דרמטיטיס ואסטמה שמקבלים דופיקסנט. ספר לרופא שלך על כל תסמין חדש בעור. הרופא שלך עשוי לשלוח אותך לרופא עור לבדיקה במקרה הצורך.
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תופעות הלוואי הנוספות הבאות דווחו:

- פריחה או אדמומיות בפנים, דלקת של כלי הדם בעור.

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העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום - סאנופי ישראל בע"מ, Greenwork Park, מתחם העסקים בקיבוץ יקום, בניין E (קומה 1), 6097600, יקום או בטלפון: 09-8633081.

להלן הקישור לאתר משרד הבריאות: https://israeldrugs.health.gov.il/#!/byDrug

בברכה,
חברת סאנופי ישראל בע"מ