



פברואר 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)

חברת סאנופי מבקשת להודיע על **עדכון התוויות, משטרי מינון והעלון לרופא** עבור התכשירים שבנדון.

ההתוויה ל- **Eosinophilic Esophagitis** הורחבה.

התוויה ל- **Chronic Obstructive Pulmonary Disease** נוספה עבור דופיקסנט 300 מ"ג.

ההתוויות המאושרות הן:

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.

העדכונים העיקריים בעלון לרופא הינם:

2. THERAPEUTIC INDICATIONS

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2.4 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).

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2.6 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.

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3. DOSAGE AND ADMINISTRATION

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3.4 Recommended Dosage for Eosinophilic Esophagitis

The recommended dosage of DUPIXENT for adult and pediatric patients 1 year of age and older, weighing at least 15 kg, is specified in table 5.

Table 5: Dosage of DUPIXENT in Adult and Pediatric Patients 1 Year of Age and Older with Eosinophilic Esophagitis

Body Weight	Recommended Dosage
15 to less than 30 kg	200 mg every other week (Q2W)
30 to less than 40 kg	300 mg every other week (Q2W)
40 kg or more	300 mg every week (QW)

Consideration should be given to discontinuing treatment in patients who have shown no response after 16 weeks of treatment for EoE.

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3.8 Recommended Dosage for Chronic Obstructive Pulmonary Disease (COPD)

The recommended dosage of DUPIXENT for adult patients is 300 mg given every other week.

Dupilumab is intended for long-term treatment. Dosing beyond 52 weeks has not been studied.

Consideration should be given to discontinuing treatment in patients who have shown no response after 52 weeks of treatment for COPD.

עדכונים נוספים לגבי יעילות ובטיחות התכשירים להתוויות הנ"ל, נוספו בסעיפים שונים על העלון.

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://israel.drugs.health.gov.il/#!/byDrug>

בברכה,
חברת סאנופי ישראל בע"מ