



יולי 2024

**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)

התוויות התכשירים עבור שני החוזקים:

**Atopic Dermatitis**

DUPIXENT is indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis 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.

התוויות נוספות עבור התכשיר דופיקסנט 300 מ"ג:

**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 300mg is indicated for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 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.



חברת סאנופי מבקשת להודיע על עדכון העלון לרופא.

העדכונים העיקריים הינם:

## 12. CLINICAL STUDIES

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### 12.2 Asthma

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**Table 20: Efficacy Results of DUPIXENT in VOYAGE**

Treatment	EOS $\geq 300$ cells/mcL <sup>a</sup>		
Annualized Severe Exacerbations Rate over 52 Weeks			
	N	Rate (95% CI)	Rate Ratio (95% CI)
DUPIXENT 100 mg Q2W <sup>b</sup> (<30 kg)/ 200 mg Q2W ( $\geq 30$ kg)	175	0.24 (0.16, 0.35)	0.35 (0.22, 0.56)
Placebo	84	0.67 (0.47, 0.95)	
Mean Change from Baseline in Percent Predicted FEV <sub>1</sub> at Week 12			
	N	LS mean $\Delta$ from Baseline	LS mean difference vs. Placebo (95% CI)
DUPIXENT 100 mg Q2W <sup>b</sup> (<30 kg)/ 200 mg Q2W ( $\geq 30$ kg)	168	10.15	5.32 (1.76, 8.88)
Placebo	80	4.83	

<sup>a</sup> This reflects the prespecified primary analysis population for VOYAGE in the United States.

<sup>b</sup> The effectiveness of DUPIXENT 300 mg Q4W was extrapolated from efficacy of 100 mg Q2W.

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העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס 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