



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 ≥ 300 cells/mcL ^a		
Annualized Severe Exacerbations Rate over 52 Weeks			
	N	Rate (95% CI)	Rate Ratio (95% CI)
DUPIXENT 100 mg Q2W ^b (<30 kg)/ 200 mg Q2W (≥ 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 ₁ at Week 12			
	N	LS mean Δ from Baseline	LS mean difference vs. Placebo (95% CI)
DUPIXENT 100 mg Q2W ^b (<30 kg)/ 200 mg Q2W (≥ 30 kg)	168	10.15	5.32 (1.76, 8.88)
Placebo	80	4.83	

^a This reflects the prespecified primary analysis population for VOYAGE in the United States.

^b 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