



נובמבר 2025

DUPIXENT 300mg solution for injection
DUPIXENT 200mg solution for injection

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.

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

Chronic Rhinosinusitis with Nasal Polyps

DUPIXENT is indicated as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (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 הרחבת ההתוויה לשימוש ב-CRSwNP לילדים מגיל 12 שנים ומעלה וכן על עדכון העלונים לרופא ולצרכן.

העדכונים העיקריים הינם:

בעלון לרופא:

2. THERAPEUTIC INDICATIONS

#####

2.3 Chronic Rhinosinusitis with Nasal Polyp~~osis~~

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

DUPIXENT is indicated as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

#####

3. DOSAGE AND ADMINISTRATION

#####

3.5 Recommended Dosage for Chronic Rhinosinusitis with Nasal Polyp~~osis~~

The recommended dosage of DUPIXENT for adult ~~patients~~ and pediatric patients 12 years of age and older is 300 mg given every 2 weeks.

#####

בנוסף, בסעיפים שונים בעלון לרופא, עודכנה דרך ביטוי גילאי המשתמשים בהתוויות השונות.



7.3 Pediatric Use

#####

CRSwNP

DUPIXENT is not indicated for the treatment of CRSwNP in pediatric subjects less than 18 years of age.

The safety and effectiveness of DUPIXENT for add-on maintenance treatment in patients with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP) have been established in pediatric patients aged 12 years and older. Use of DUPIXENT for this indication is supported by evidence from adequate and well-controlled studies of DUPIXENT as add-on maintenance treatment in adults with inadequately controlled CRSwNP (SINUS-24 and SINUS-52) with the following additional data:

- Pharmacokinetic (PK) data from adult and pediatric patients aged 12 years and older with moderate-to-severe asthma and adult patients with inadequately controlled CRSwNP
- Safety data in pediatric patients aged 12 years and older with moderate-to-severe asthma [see Adverse Reactions (6.1), Clinical Pharmacology (10.3), and Clinical Studies (12.3)]

Safety and effectiveness of DUPIXENT have not been established in pediatric patients younger than 12 years of age with CRSwNP.

#####

10.3 Pharmacokinetics

#####

CRSwNP

Clinical studies have not been conducted in pediatric patients aged 12 years and older with CRSwNP. Dupilumab exposures are expected to be comparable between adults and pediatric patients aged 12 years and older at the recommended dosage for CRSwNP (300 mg every 2 weeks).

#####

בעלונים לצרכן של מזרקי ועטי הזרקה של דופיקסנט 300 מ"ג:

1. למה מיועדת התרופה?

#####

- בשילוב עם תרופות נוספות כדי לטפל בדלקת כרונית בסינוסים עם פוליפים באף במבוגרים **וילדים מגיל 12 שנים ומעלה**, שמחלתם אינה נמצאת בשליטה.

#####

3. כיצד תשתמש בתרופה?

מינון למבוגרים וילדים מגיל 12 שנים ומעלה עם דלקת כרונית בסינוסים עם פוליפים באף

המינון המומלץ הוא 300 מ"ג כל שבועיים.



העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום - סאנופי ישראל בע"מ, Greenwork Complex, 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