מרץ 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.

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חברת סאנופי מבקשת להודיע על עדכון העלונים לצרכן ולרופא.

עבור העלון לרופא - העדכונים העיקריים הינם בנושא

Atopic Dermatitis with Hand and/or Foot Involvement

6.1 Clinical Trials Experience

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Atopic Dermatitis with Hand and/or Foot Involvement

The safety of DUPIXENT was assessed in a 16-week, multicenter, randomized, double-blind, parallel-group, placebo-controlled trial (Liberty-AD-HAFT) in 133 adult and pediatric subjects 12 to 17 years of age with atopic dermatitis with moderate-to-severe hand and/or foot involvement [*see Clinical Studies (12)*]. In this trial 67 subjects received DUPIXENT, and 66 subjects received placebo. DUPIXENT-treated subjects received the recommended dosage based on their age and body weight [*see Dosage and Administration (3.3)*]. The safety profile of DUPIXENT in these subjects through Week 16 was consistent with the safety profile from studies in adult and pediatric subjects 6 months of age and older with moderate-to-severe AD.

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7.3 Pediatric Use

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- Liberty-AD-HAFT which included 27 pediatric subjects 12 to 17 years of age with atopic dermatitis with moderate-to-severe hand and/or foot involvement treated with DUPIXENT (N=14) or matching placebo (N=13)

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12. CLINICAL STUDIES

Atopic Dermatitis with Hand and/or Foot Involvement

The efficacy and safety of DUPIXENT was evaluated in a 16-week, multicenter, randomized, double-blind, parallel-group, placebo-controlled trial (Liberty-AD-HAFT) in 133 adult and pediatric subjects 12 to 17 years of age with atopic dermatitis with moderate-

to- severe hand and/or foot involvement, defined by an established diagnosis of atopic dermatitis and screening to rule out irritant and allergic contact dermatitis through history and appropriate patch testing, and by an IGA (hand and foot) score ≥3 (scale of 0 to 4) and a hand and foot Peak Pruritus Numeric Rating Scale (NRS) score for maximum itch intensity ≥4 (scale of 0 to 10).

Fifty-three (53) percent (N=70/133) of the subjects also had moderate-to-severe AD outside of the hands or feet (IGA global ≥3). Eligible subjects had previous inadequate response or intolerance to treatment of hand and/or foot dermatitis with topical AD medications. In this trial 67 subjects received DUPIXENT, and 66 subjects received placebo. DUPIXENT-treated subjects received the recommended dosage based on their age and body weight *[see Dosage and Administration (3.3)]*. Subjects were not allowed concomitant use of topical treatments for AD on the hands and feet during the trial, but were allowed the use of topical treatments for AD on other parts of the body with certain restrictions.

In Liberty-AD-HAFT, 38% of subjects were male, 80% were White, 13% were Asian, and 5% were Black or African American. For ethnicity, 4% were identified as Hispanic or Latino and 96% were identified as not Hispanic or Latino. Seventy-two (72) percent (N=96/133) of subjects had a baseline IGA (hand and foot) score of 3 (atopic dermatitis with moderate hand and/or foot involvement), and 28% (N=37/133) of subjects had a baseline IGA (hand and foot) score of 4 (atopic dermatitis with severe hand and/or foot involvement). The baseline weekly averaged hand and foot Peak Pruritus NRS score was 7.1.

The primary endpoint was the proportion of subjects with an IGA hand and foot score of 0 (clear) or 1 (almost clear) at Week 16. The key secondary endpoint was reduction of itch as measured by the hand and foot Peak Pruritus NRS (≥4-point improvement).

The efficacy results at Week 16 for Liberty-AD-HAFT are presented in Table 15.

Table 15: **Efficacy Results of DUPIXENT in Liberty-AD-HAFT at Week 16 (FAS)[a] in Adult and Pediatric Subjects 12 to 17 Years of Age with AD with Moderate- to-Severe Hand and/or Foot Involvement**

	DUPIXENT 200/300 mg Q2W[d] (N=67)[a]	**Placebo (N=66)[a]**	**Difference vs. Placebo (95 % CI)**
IGA (hand and foot) 0 or 1[b,c]	40%	17%	24% (9%, 38%)
Improvement (reduction) of weekly averaged hand and foot Peak Pruritus NRS ≥4[c]	52%	14%	39% (24%, 53%)

CI = confidence interval

[a] Full Analysis Set (FAS) includes all subjects randomized.

[b] Responder was defined as a subject with an IGA 0 or 1 ("clear" or "almost clear").

[c] Subjects who received rescue treatment (21% and 3% in the placebo and DUPIXENT arms, respectively) or with missing data were considered as non-responders.

[d] Adults received a loading dose of DUPIXENT 600 mg SC followed by 300 mg SC Q2W. Pediatric subjects 12 to 17 years of age received a loading dose of DUPIXENT 600 mg SC followed by 300 mg SC Q2W (for body weight ≥60 kg) or a loading dose of DUPIXENT 400 mg SC followed by 200 mg SC Q2W (for body weight <60 kg).

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העלון ובו מסומנים העדכונים מצורף למכתב זה.

עבור העלון לצרכן – העדכונים העיקריים הינם:

4. תופעות לוואי

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תופעות הלוואי השכיחות ביותר של דופיקסנט:

- .....
- יובש בעין
- .....

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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

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