

**DUPIXENT**<sup>®</sup>  
(dupilumab) Injection  
200mg · 300mg

## INDICATION

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).

THE FIRST AND ONLY FDA-APPROVED TREATMENT FOR EoE PATIENTS AS YOUNG AS 1 YEAR

# TRANSFORM THE WAY YOU MANAGE EoE



Not actual patients.

Discover clinical, histologic, endoscopic, and safety results  
for pediatric patients<sup>1,2</sup>

## IMPORTANT SAFETY INFORMATION

**CONTRAINDICATION:** DUPIXENT is contraindicated in patients with known hypersensitivity to dupilumab or any of its excipients.

## WARNINGS AND PRECAUTIONS

**Hypersensitivity:** Hypersensitivity reactions, including anaphylaxis, serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

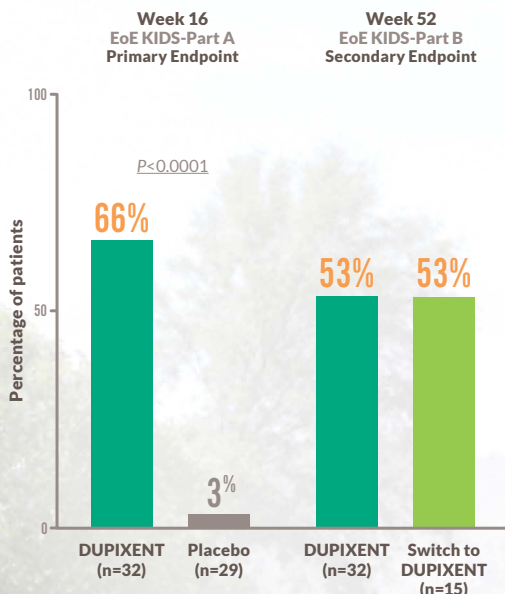
Please see additional Important Safety Information throughout and accompanying full Prescribing Information [here](#).

# DEMONSTRATED GREATER HISTOLOGIC IMPROVEMENTS IN CHILDREN AS YOUNG AS 1 YEAR<sup>1,2</sup>

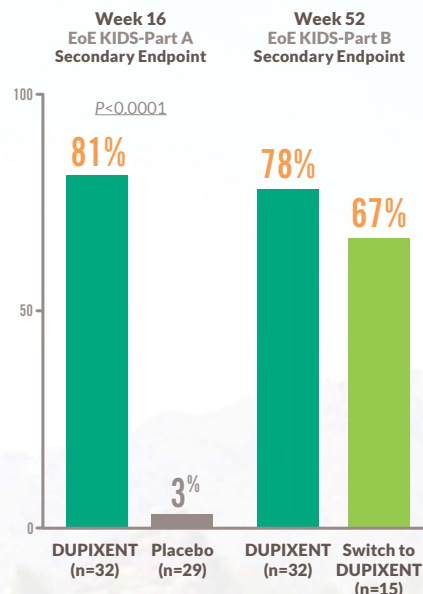
# VISIBLE IMPROVEMENTS IN THE ESOPHAGUS WERE OBSERVED<sup>2</sup>

## Histologic improvements were observed at Weeks 16 and 52 with DUPIXENT<sup>1,2</sup>

### Histologic Remission<sup>1,2</sup> (≤6 EOS/HPF peak esophageal intraepithelial EOS count)



### Histologic Response<sup>1,2</sup> (<15 EOS/HPF peak esophageal intraepithelial EOS count)



Results are descriptive in the extended active treatment period at Week 52. Definitive conclusions cannot be made due to limitations associated with extended active treatment design, including lack of comparator arm and decreasing sample size.<sup>2</sup>

## IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS (cont'd)

### Risk Associated with Abrupt Reduction of Corticosteroid Dosage:

Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of DUPIXENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a healthcare provider. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

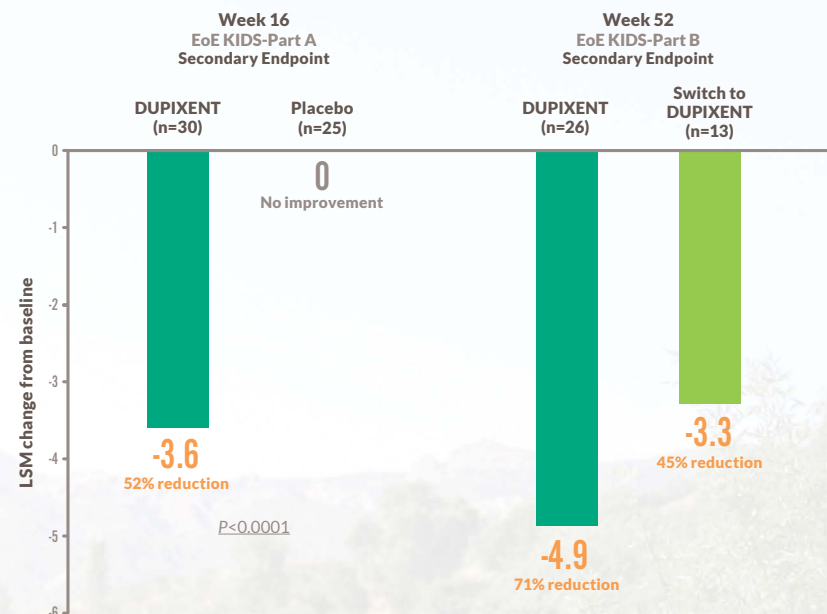
**Patients with Co-morbid Asthma:** Advise patients with co-morbid asthma not to adjust or stop their asthma treatments without consultation with their physicians.

EOS, eosinophil; EOS/HPF, eosinophils per high-power field.

Not an actual patient.

## Improvements in EREFS total scores were observed at Weeks 16 and 52 with DUPIXENT<sup>2</sup>

### Reduction in EREFS total score<sup>2,a</sup>



Thresholds for clinically meaningful changes in EREFS scores have not been established. Results are descriptive in the extended active treatment period at Week 52. Definitive conclusions cannot be made due to limitations associated with extended active treatment design, including lack of comparator arm and decreasing sample size.<sup>2</sup>

<sup>a</sup> Reductions indicate improvements in score.<sup>2</sup>

## IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS (cont'd)

**Arthralgia and Psoriatic Arthritis:** Arthralgia has been reported with the use of DUPIXENT with some patients reporting gait disturbances or decreased mobility associated with joint symptoms; some cases resulted in hospitalization. Cases of new-onset psoriatic arthritis requiring systemic treatment have been reported with the use of DUPIXENT. Advise patients to report new-onset or worsening joint symptoms. If symptoms persist or worsen, consider rheumatological evaluation and/or discontinuation of DUPIXENT.

EREFs, Endoscopic Reference Scores; LSM, least squares mean.

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# DECREASE IN SIGNS AND SYMPTOMS WERE REPORTED BY CAREGIVERS<sup>1,2</sup>

# CHANGES IN BODY WEIGHT FOR AGE PERCENTILE WERE STUDIED<sup>2</sup>

## Decrease in the number of days with ≥1 sign or symptom of EoE via PESQ-C<sup>1,2,a</sup>



Definitive conclusions cannot be made. Numerical improvements were observed at Week 16 and maintained for 52 weeks. Results are descriptive at Week 52 due to limitations associated with extended active treatment design, including lack of comparator arm and decreasing sample size.<sup>2</sup>

<sup>a</sup> Baseline number of days with EoE symptoms out of a 14-day period was 6.0 days in the DUPIXENT arm and 6.9 days in the placebo arm.<sup>2</sup>

## PESQ-C measures the presence of signs and symptoms of EoE in children<sup>2,3</sup>

Pediatric EoE Signs/Symptoms Questionnaire-Caregiver (PESQ-C) is a novel questionnaire designed with expert guidance to recognize 8 distinct signs and symptoms of EoE over a 14-day period by caregivers:

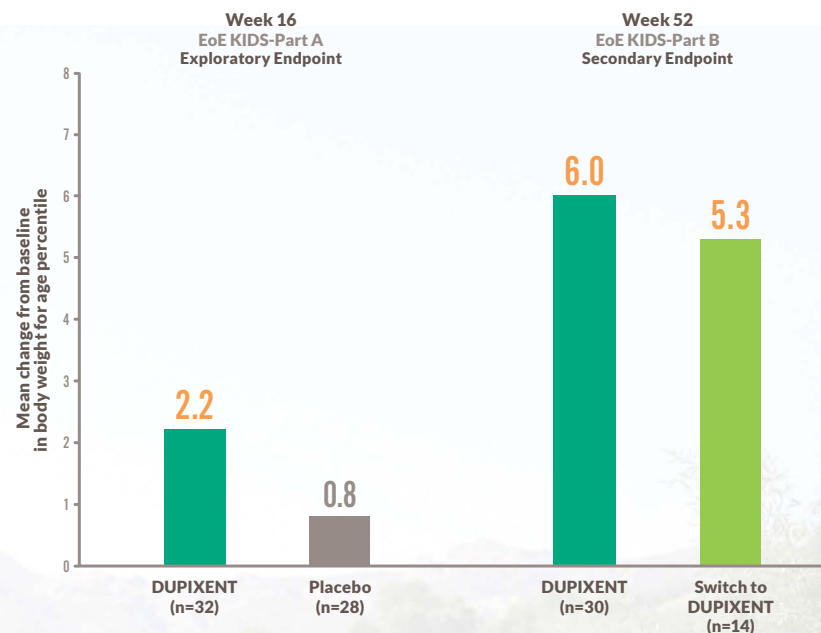
- Stomach pain
- Heartburn
- Acid reflux
- Regurgitation
- Vomiting
- Difficulty swallowing
- Food getting stuck
- Food refusal

- Caregiver responses reflect what their child has told them, what they have directly observed, and/or what another caregiver has told them<sup>2,3</sup>
- Total score ranges from 0 to 1. For example, if the patient has 7 days of symptoms over the 14-day period, the total score is 0.50 (calculated by 7÷14)<sup>2,3</sup>

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## Changes in body weight for age percentile<sup>2,b</sup>



Results are descriptive. Definitive conclusions cannot be made due to the exploratory nature of the results at Week 16, and lack of comparator arm and decreasing sample size at Week 52.<sup>2</sup>

<sup>b</sup> Body weight for age percentile, standardized by gender and age, is used to assess a child's weight compared to their peers.

## IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS (cont'd)

**Parasitic (Helminth) Infections:** It is unknown if DUPIXENT will influence the immune response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with DUPIXENT. If patients become infected while receiving treatment with DUPIXENT and do not respond to anti-helminth treatment, discontinue treatment with DUPIXENT until the infection resolves.

**Vaccinations:** Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating DUPIXENT. Avoid use of live vaccines during treatment with DUPIXENT.



Not an actual patient.

# DEMONSTRATED SAFETY PROFILE IN CHILDREN AS YOUNG AS 1 YEAR<sup>1,2</sup>

# THE PIVOTAL PEDIATRIC TRIAL ENROLLED CHILDREN AS YOUNG AS 1 YEAR<sup>1,2</sup>

Adverse events occurring in ≥5% of patients aged 1-11 years treated with DUPIXENT and greater than placebo through 16 weeks<sup>2</sup>

	DUPIXENT (n=32)   n(%)	Placebo (n=29)   n(%)
Injection site erythema	4 (13)	1 (3)
COVID-19 <sup>a</sup>	3 (9)	0
Viral gastroenteritis	2 (6)	1 (3)
Diarrhea	2 (6)	1 (3)
Pyrexia	2 (6)	1 (3)
Fatigue	2 (6)	0

<sup>a</sup> All cases were mild or moderate and did not lead to study discontinuation.<sup>2</sup>

The safety profile of DUPIXENT through Week 16 of the EoE KIDS clinical study was generally similar to the safety profile in adult and pediatric patients 12 years of age and older with EoE. In Part B, a helminth infection was reported in one DUPIXENT-treated subject.<sup>1</sup>

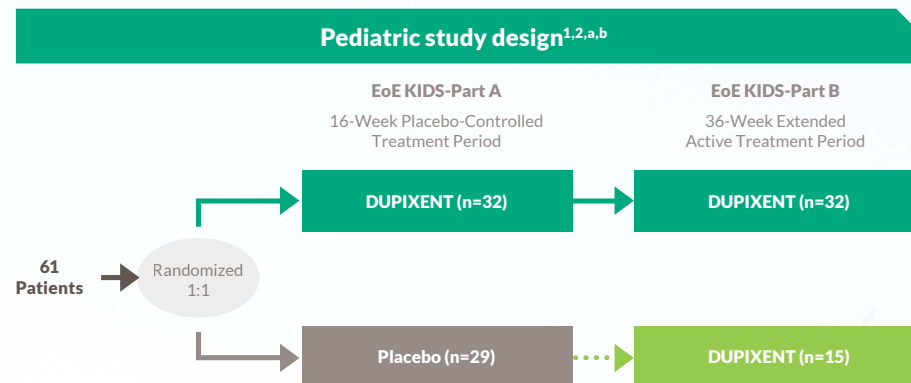
## IMPORTANT SAFETY INFORMATION

**ADVERSE REACTIONS:** The most common adverse reactions (incidence ≥2%) in patients with EoE are injection site reactions, upper respiratory tract infections, arthralgia, and herpes viral infections.

### USE IN SPECIFIC POPULATIONS

- Pregnancy:** A pregnancy exposure registry monitors pregnancy outcomes in women exposed to DUPIXENT during pregnancy. To enroll or obtain information call 1-877-311-8972 or go to <https://mothertobaby.org/ongoing-study/dupixent/>. Available data from case reports and case series with DUPIXENT use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, DUPIXENT may be transmitted from the mother to the developing fetus.
- Lactation:** There are no data on the presence of DUPIXENT in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DUPIXENT and any potential adverse effects on the breastfed child from DUPIXENT or from the underlying maternal condition.

The efficacy and safety of DUPIXENT were evaluated in patients aged 1-11 years weighing ≥15 kg in a multipart, phase 3 trial for up to 52 weeks<sup>1,2</sup>



- EoE KIDS-Part A:** A 16-week, double-blind, placebo-controlled trial. Subjects were randomized to receive either DUPIXENT or placebo at dosing regimens based on body weight: ≥15 to <30 kg (200 mg Q2W) and ≥30 to <60 kg (300 mg Q2W)<sup>1,2</sup>
- EoE KIDS-Part B:** A 36-week active treatment extension study, for a total of 52 weeks of treatment in subjects who were treated with DUPIXENT or placebo, completing Part A. Subjects received DUPIXENT at dosing regimens based on body weight: ≥15 to <30 kg (200 mg Q2W), ≥30 to <60 kg (300 mg Q2W), and ≥60 kg (300 mg QW)<sup>1,2</sup>
- All enrolled subjects were required to have uncontrolled EoE (≥15 intraepithelial EOS/HPF despite an 8-week course of a high-dose PPI) and a history of EoE signs and symptoms<sup>1,2</sup>

<sup>a</sup> The 300 mg Q2W dosing regimen is lower than the recommended dosage of DUPIXENT in subjects ≥40 kg.<sup>1</sup>

<sup>b</sup> A lower exposure DUPIXENT arm was studied in Part A (n=26) and Part B (n=36), but is not approved for the treatment of EoE.<sup>2</sup>

PPI, proton pump inhibitor; QW, once weekly; Q2W, once every 2 weeks.

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# WEIGHT-BASED DOSING AND OPTION TO ADMINISTER AT HOME OR IN OFFICE<sup>1</sup>

# DUPIXENT ATTRIBUTES AND CONSIDERATIONS<sup>1</sup>

## Weight-tiered dosage regimen<sup>1</sup>



1+ YEAR OF AGE

No loading dose

15 to <30 kg	Every 2 weeks	200 mg <sup>a</sup> 1 pre-filled pen or syringe
30 to <40 kg	Every 2 weeks	300 mg <sup>b</sup> 1 pre-filled pen or syringe
≥40 kg <sup>c</sup>	Every week	300 mg <sup>b</sup> 1 pre-filled pen or syringe

<sup>a</sup> 200 mg=1.14 mL solution.

<sup>b</sup> 300 mg=2 mL solution.

<sup>c</sup> The recommended dosage of 300 mg QW for pediatric subjects 1 to 11 years of age weighing ≥40 kg is based on modeled pharmacokinetic data to provide comparable exposures to the 300 mg QW dosage in adult and pediatric subjects 12 years of age and older weighing ≥40 kg with EoE.<sup>1</sup>

## Administration options<sup>1</sup>



Available in a 200 mg and 300 mg pre-filled pen (for indicated patients 2+ years of age) or pre-filled syringe (for indicated patients 1+ year of age) for subcutaneous injection<sup>1</sup>

- DUPIXENT is administered by subcutaneous injection and is intended for use under the guidance of a healthcare provider<sup>1</sup>
- In children 1 year to less than 12 years of age, DUPIXENT should be given by a caregiver<sup>1</sup>
- Provide proper training to patients and/or caregivers on the preparation and administration of DUPIXENT prior to use, according to the Instructions for Use<sup>1</sup>
- Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with DUPIXENT<sup>1</sup>

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### NO BOXED WARNING

Please see additional Warnings and Precautions in the Prescribing Information and Important Safety Information throughout.



### NO KNOWN DRUG-TO-DRUG INTERACTIONS

- Not metabolized through the liver or excreted through the kidneys



### DUPIXENT IS NOT AN IMMUNOSUPPRESSANT



### NO REQUIREMENT FOR INITIAL LAB TESTING OR ONGOING LAB MONITORING

according to the Prescribing Information

## IMPORTANT SAFETY INFORMATION SELECT WARNING AND PRECAUTION

**Hypersensitivity:** Hypersensitivity reactions, including anaphylaxis, serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

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**References:** 1. DUPIXENT Prescribing Information. 2. Data on file, Regeneron Pharmaceuticals, Inc. 3. Kamat S, Yaworsky A, Guillemin I, et al. Novel questionnaires for assessing signs and symptoms of eosinophilic esophagitis in children. *J Allergy Clin Immunol Pract.* 2022;10(7):1856-1863.e3. 4. Bredenoord AJ, Patel K, Schoepfer AM, et al. Disease burden and unmet need in eosinophilic esophagitis. *Am J Gastroenterol.* 2022;117(8):1231-1241. 5. O'Shea KM, Aceves SS, Dellon ES, et al. Pathophysiology of eosinophilic esophagitis. *Gastroenterology.* 2018;154(2):333-345. 6. Hill DA, Spergel JM. The immunologic mechanisms of eosinophilic esophagitis. *Curr Allergy Asthma Rep.* 2016;16(2):9. doi: 10.1007/s11882-015-0592-3 7. Data on file, 2024 IQVIA SANOFI.



Not actual patients.

**Choose the first and only EoE treatment for children as young as 1 year<sup>1</sup>**

**Long-term results in 3 key areas of EoE management<sup>1,2</sup>:**



**CLINICAL**

Frequency of symptoms and monitoring weight



**HISTOLOGIC**

Changes in eosinophilic inflammation



**ENDOSCOPIC**

Visible improvements in the esophagus



**DUPIXENT INHIBITS IL-4 AND IL-13 SIGNALING, TARGETING TWO OF THE KEY SOURCES OF UNDERLYING TYPE 2 INFLAMMATION IN EoE<sup>1,4-6</sup>**

The mechanism of dupilumab action has not been definitively established.<sup>1</sup>



**DEMONSTRATED SAFETY PROFILE IN CHILDREN AS YOUNG AS 1 YEAR WITH EoE<sup>1,2</sup>**

The most common adverse reactions were injection site reactions.

**OVER 45,000**

**EoE PATIENTS TREATED SINCE APPROVAL IN 2022<sup>1,7,a</sup>**



**DUPIXENT IS NOT AN IMMUNOSUPPRESSANT<sup>1</sup>**



**DISCOVER  
DUPIXENT**



<sup>a</sup>The number of patients who have filled at least 1 DUXIPENT prescription for EoE based on IQVIA National Source of Business (NSOB) data as of February 2025.<sup>7</sup>

Not actual patients.

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