DUPIXENT®
(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).

Discover clinical, histologic, endoscopic, and safety results for adult and adolescent patients[1-3]

IMPORTANT SAFETY INFORMATION

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

WARNINGS AND PRECAUTIONS

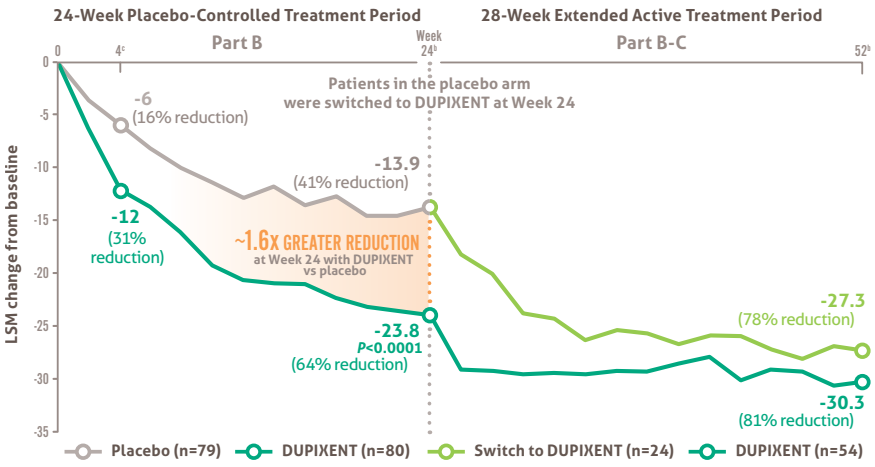
Hypersensitivity: Hypersensitivity reactions, including anaphylaxis, serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported. If a clinically significant hypersensitivity reaction occurs, institute appropriate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

Please see additional Important Safety Information throughout and accompanying full Prescribing Information here.

DUPIXENT REDUCED THE FREQUENCY AND SEVERITY OF DYSPHAGIA SYMPTOMS[1,2]

64% reduction in DSQ score at Week 24 and 81% reduction at Week 52[a,b]

Dysphagia Symptom Questionnaire (DSQ) total score in Parts B and B-C[a-c]



Part A

- **Week 4[c]: -9–point reduction (28%)** from baseline with DUPIXENT (n=42) vs **-4–point reduction (11%)** with placebo (n=39)
- **Week 24[b]: -21.9–point reduction (69%)** from baseline with DUPIXENT (n=42) vs **-9.6–point reduction (32%)** with placebo (n=39) (*P*<0.001)

Part A-C

- **Week 52[b]: -23.4–point reduction (76%)** from baseline after 52 weeks of treatment with DUPIXENT (n=29)
- **Week 52[b]: -21.7–point reduction (66%)** from baseline after switching to DUPIXENT from placebo at Week 24 (n=23)

Extended active treatment period, results are descriptive 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.

Please see Study Design on Page 6.

[a] Total biweekly DSQ scores range from 0 to 84; higher scores indicate greater frequency and severity of dysphagia.
[b] Coprimary endpoint at Week 24; secondary endpoint at Week 52.
[c] Week 4 assessment is a post hoc analysis; results are descriptive.

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.

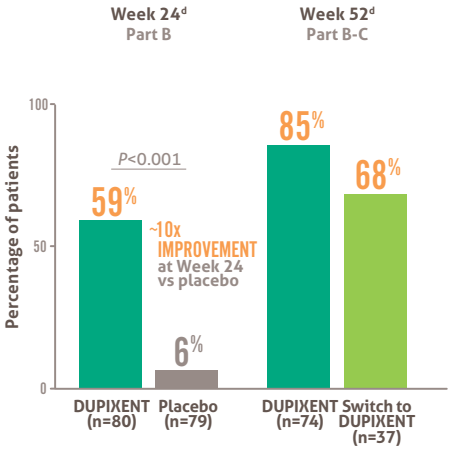
Patients with Co-morbid Asthma: Advise patients with co-morbid asthma not to adjust or stop their asthma treatments without consultation with their physicians.

LSM, least squares mean.

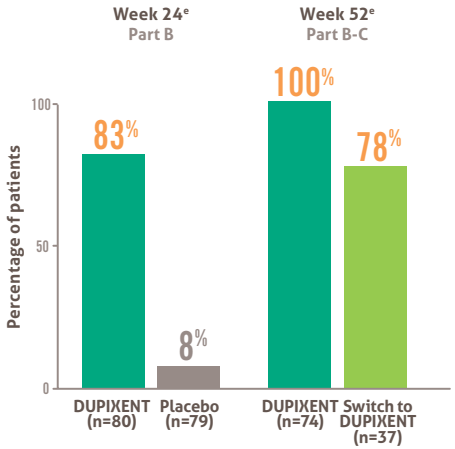
DUPIXENT DEMONSTRATED GREATER HISTOLOGIC IMPROVEMENTS[1,2]

59% of patients demonstrated histologic remission at Week 24 and 85% at Week 52[d]

Histologic Remission (≤6 EOS/HPF peak esophageal intraepithelial EOS count)



Histologic Response (<15 EOS/HPF peak esophageal intraepithelial EOS count)



Histologic Remission[d]

- **Week 24 (Part A): 60% of patients** with DUPIXENT (n=42) vs **5%** with placebo (n=39) (*P*<0.001)
- **Week 52 (Part A-C): 56% of patients** after 52 weeks of treatment with DUPIXENT (n=34) and **60%** after switching to DUPIXENT from placebo at Week 24 (n=30)

Histologic Response[e]

- **Week 24 (Part A): 64% of patients** with DUPIXENT (n=42) vs **8%** with placebo (n=39)
- **Week 52 (Part A-C): 82% of patients** after 52 weeks of treatment with DUPIXENT (n=34) and **70%** after switching to DUPIXENT from placebo at Week 24 (n=30)

Extended active treatment period, results are descriptive 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.

[d] Coprimary endpoint at Week 24; secondary endpoint at Week 52.
[e] Secondary endpoint at Weeks 24 and 52. In Part B, this endpoint was ordered after the point at which hierarchical testing procedure failed; results are descriptive.

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.

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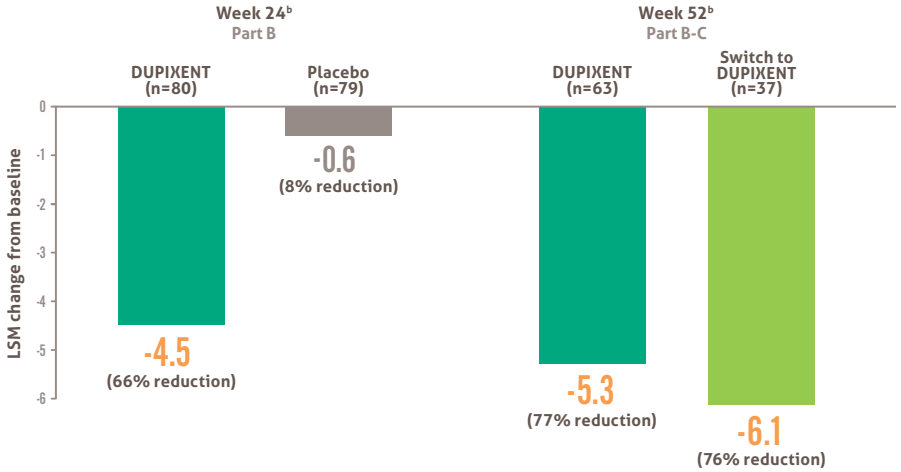
VISIBLE CHANGES IN THE ESOPHAGUS WERE OBSERVED[2]

EREFS total score was reduced at Weeks 24 and 52[b]

Reduction in EREFS total score



Part A

- **Week 24[b]: -3.2–point reduction (49%)** from baseline with DUPIXENT (n=42) vs **-0.3–point reduction (5%)** with placebo (n=39)

Part A-C

- **Week 52[b]: -4.1–point reduction (63%)** from baseline after 52 weeks of treatment with DUPIXENT (n=35)
- **Week 52[b]: -3.9–point reduction (65%)** from baseline after switching to DUPIXENT from placebo at Week 24 (n=30)

Extended active treatment period, results are descriptive 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.

[b] **Secondary endpoint at Weeks 24 and 52. Results are descriptive; thresholds for clinically meaningful changes in EREFS scores have not been established. Additionally, in Part B this endpoint was ordered after the point at which hierarchical testing procedure failed.**

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information here.

DEMONSTRATED SAFETY PROFILE UP TO 52 WEEKS[1,2]

Adverse reactions occurring in ≥2% of patients treated with DUPIXENT QW in Parts A and B and greater than placebo (24-week safety pool)

	DUPIXENT QW (n=122) | n (%)	Placebo QW (n=117) | n (%)
Injection site reactions[a]	46 (38%)	39 (33%)
Upper respiratory tract infections[b]	22 (18%)	12 (10%)
Arthralgia	3 (2%)	1 (1%)
Herpes viral infections[c]	3 (2%)	1 (1%)

[a] Injection site reactions include, but are not limited to, injection site swelling, pain, and bruising.
[b] Upper respiratory tract infections are composed of several terms including, but not limited to, COVID-19, sinusitis, and upper respiratory tract infection.
[c] Herpes viral infections are composed of oral herpes and herpes simplex.

The safety profile of DUPIXENT was similar in Parts A and B between adults and 72 pediatric subjects aged 12 to 17 years, weighing ≥40 kg.

The most frequently reported TEAEs (in ≥5% of participants overall) during Part A-C were: injection site reaction (15.6%), injection site erythema (11.7%), injection site pain (6.5%), headache (6.5%), nasopharyngitis (5.2%), acne (5.2%), and insomnia (5.2%).[2]

The most frequently reported TEAEs (in ≥5% of participants overall) during Part B-C were: injection site reaction (13.7%), injection site pain (8.4%), injection site erythema (6.6%), and COVID-19 (7.9%).[2]

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.

TEAE, treatment-emergent adverse event.

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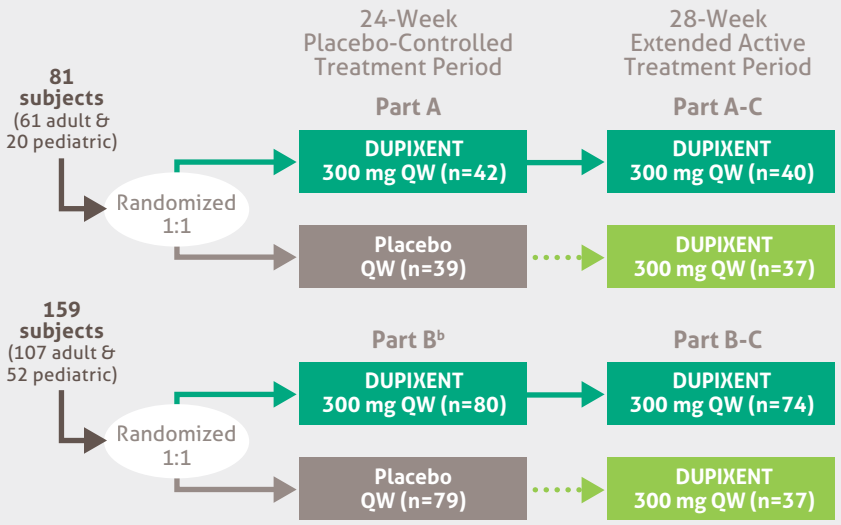
DUPIXENT WAS STUDIED IN A MULTIPART, PHASE 3 CLINICAL TRIAL[1-3]

Study design



- **Parts A and B:** Two 24-week, double-blind, placebo-controlled trials. Subjects were randomized to receive either DUPIXENT 300 mg QW, DUPIXENT 300 mg Q2W (Parts B and B-C only), or placebo QW[b]
- **Part C:** An optional 28-week active treatment extension study, for a total of 52 weeks of treatment in subjects who were treated with 300 mg DUPIXENT or placebo, completing Parts A or B
- All enrolled subjects (81 in Part A and 159 in Part B) were required to have:
  - Uncontrolled EoE as defined by ≥15 intraepithelial EOS/HPF despite 8-week course of a high-dose PPI
  - Dysphagia Symptom Questionnaire (DSQ) score ≥10

Patients who enrolled were uncontrolled despite PPI use[1,2]

Part A Patient Demographics: Mean age: 31.5 years; male: 60.5%; mean EoE duration: 5.0 years; prior swallowed topical steroid use: 74.1%; prior esophageal dilations: 43.2%; PPI use at randomization: 67.9%; food elimination diet at screening: 40.7%; mean DSQ score (range[c]: 0-84): 33.6; mean peak esophageal intraepithelial EOS count of 3 regions: 89.3; mean EREFS total score (range[c]: 0-18): 6.3.

Part B Patient Demographics: Mean age: 28.1 years; male: 63.8%; mean EoE duration: 5.6 years; prior swallowed topical steroid use: 73.3%; prior esophageal dilations: 35.4%; PPI use at randomization: 72.5%; food elimination diet at screening: 37.1%; mean DSQ score (range[c]: 0-84): 36.7; mean peak esophageal intraepithelial EOS count of 3 regions: 87.1; mean EREFS total score (range[c]: 0-18): 7.2.

[b] DUPIXENT 300 mg Q2W was studied in Part B (n=81) and Part B-C (n=116) but is not approved for the treatment of EoE.

[c] Higher score indicates greater disease severity.

EOS, eosinophil; EREFS, endoscopic reference score; QW, once weekly; Q2W, once every 2 weeks.

DOSAGE AND IMPORTANT CONSIDERATIONS FOR DUPIXENT[1]

Weight-tiered dosage regimen[1]

1+ YEAR OF AGE

No loading dose

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

[a] 200 mg=1.14 mL solution.

[b] 300 mg=2 mL solution.

[c] 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.[1]

Important considerations

NO BOXED WARNING

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

Other attributes

DUPIXENT is not an immunosuppressant

No requirement for initial lab testing or ongoing lab monitoring, according to the Prescribing Information

IMPORTANT SAFETY INFORMATION

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.

References: 1. DUPIXENT Prescribing Information. **2.** Data on file, Regeneron Pharmaceuticals, Inc. **3.** Dellon ES, Rothenberg ME, Collins MH, et al. Dupilumab in adults and adolescents with eosinophilic esophagitis. *N Engl J Med.* 2022;387(25):2317-2330. **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, 2023. IQVIA SANOFI.

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TRANSFORM THE WAY YOU MANAGE EoE

for your patients 1+ years, weighing ≥15kg

Choose DUPIXENT for your appropriate EoE patients as young as 1 year

LONG-TERM RESULTS IN 3 KEY AREAS OF EoE MANAGEMENT[1,2]

CLINICAL
Changes in frequency and severity of symptoms

HISTOLOGIC
Changes in eosinophilic inflammation

ENDOSCOPIC
Visible changes in the esophagus

DUPIXENT INHIBITS TWO OF THE KEY SOURCES UNDERLYING TYPE 2 INFLAMMATION IN EoE[1,4-6]

IL-4 IL-13

The mechanism of dupilumab action has not been definitively established.[1]

DEMONSTRATED SAFETY PROFILE[1,2]

The most common adverse reactions (incidence ≥2%) are injection site reactions, upper respiratory tract infections, arthralgia, and herpes viral infections.

OVER 45,000
EoE PATIENTS TREATED SINCE APPROVAL IN 2022[1,7,d]

DUPIXENT IS NOT AN IMMUNOSUPPRESSANT[1]

EXPLORE DUPIXENT FOR APPROPRIATE PATIENTS WITH EoE[1,2]

[d]The number of patients who have filled at least 1 DUPIXENT prescription for EoE based on IQVIA National Source of Business (NSOB) data as of February 2025.[24]

IMPORTANT SAFETY INFORMATION

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

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