WHEN TOPICAL Rx THERAPIES ARE NOT ENOUGH IN UNCONTROLLED MODERATE-TO-SEVERE ATOPIC DERMATITIS PATIENTS 6+ MONTHS OF AGE

CHANGE THEIR STORY TOGETHER

BY PARTNERING WITH A SPECIALIST

Real patients being treated with DUPIXENT. Individual results may vary.

6+ MONTHS OF AGE

DUPIXENT IS THE FIRST AND ONLY BIOLOGIC APPROVED FROM INFANCY TO ADULTHOOD

FOR UNCONTROLLED MODERATE-TO-SEVERE ATOPIC DERMATITIS

STUCK IN A CYCLE OF FLARE, TREAT, REPEAT?

ARE THEY DU? FOR A CHANGE

IDENTIFY PATIENTS WHO MAY BENEFIT FROM SEEING A DERMATOLOGIST OR ALLERGIST

PARTNER WITH A SPECIALIST

INDICATION

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.

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 click here for full Prescribing Information.

DUPIXENT® (dupilumab) Injection

200mg · 300mg

ARE YOUR PATIENTS DU FOR A CHANGE?

Patient identification

Per American Academy of Dermatology treatment guidelines, appropriate adult patients with uncontrolled moderate-to-severe atopic dermatitis may be candidates for systemic therapies such as DUPIXENT.[1]

Consider partnering with a specialist for your patients aged 6+ months if they:

- Have given **≥1 topical Rx therapy** an adequate trial but are still uncontrolled[1-3,a]
- Feel that their **itch is not well controlled**[3,4]
- Have **≥10% of their body covered** with lesions and/or lesions that may involve problem areas, such as the face, hands, and feet[1,2,5]

The photos above are not intended to represent baseline before DUPIXENT treatment.

ARE THEY DU? FOR A CHANGE

Ask yourself 2 simple questions to assess your patients aged 6+ months with moderate-to-severe atopic dermatitis uncontrolled with topical Rx therapy

DU they still itch? *or* **DU they** still have burdensome lesions?

If you answer **"Yes" to either of these questions,**
THEY MAY BE DU FOR DUPIXENT

[a]According to an expert panel of the International Eczema Council, adequate topical Rx therapy is defined as an induction period (to gain control of a flare) with medium- to high-potency topical corticosteroids (TCS) applied once or twice daily for 1 to 4 weeks, followed by a proactive maintenance period with medium-potency TCS applied 2 or 3 times weekly to normal-appearing skin at sites of frequent flare.[3]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Conjunctivitis and Keratitis: Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received DUPIXENT versus placebo. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered or were recovering during the treatment period. Conjunctivitis and keratitis have been reported with DUPIXENT in postmarketing settings, predominantly in atopic dermatitis patients. Some patients reported visual disturbances (e.g., blurred vision) associated with conjunctivitis or keratitis. Advise patients to report new onset or worsening eye symptoms to their healthcare provider. Consider ophthalmological examination for patients who develop conjunctivitis that does not resolve following standard treatment or signs and symptoms suggestive of keratitis, as appropriate.

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.

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PROVEN ITCH REDUCTION AND SKIN CLEARANCE

Itch relief and skin clearance in clinical trials across ages 6+ months that included monotherapy and concomitant TCS[2,6,7]

Real patients being treated with DUPIXENT. Individual results may vary.

	6 months-5 years AD-1539 (Week 16)		18+ years of age CHRONOS (Week 16)	
	200/300 mg Q4W		300 mg Q2W	
	DUPIXENT + TCS (n=83)	Placebo + TCS (n=79)	**DUPIXENT + TCS** (n=106)	Placebo + TCS (n=315)
Secondary endpoints ≥75% improvement in lesion extent and severity (EASI-75) (% of patients)	**53%** *P*<0.0001	11%	**69%** *P*<0.0001	23%
≥4-point improvement in Worst Scratch/Itch NRS in infants to preschoolers (6 months-5 years) and Peak Pruritus NRS in adults (% of patients)	**48%** *P*<0.0001	9%	**59%** *P*<0.0001	20%

Primary endpoint was the proportion of subjects with an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) and, in adults, ≥2-point improvement at Week 16[2,6,7]:

- **28%** of patients 6 months to 5 years of age treated with DUPIXENT + TCS vs **4%** with placebo + TCS in AD-1539, *P*<0.0001
- **39%** of patients 18+ years of age treated with DUPIXENT + TCS vs **12%** with placebo + TCS in CHRONOS, *P*<0.0001

The results presented are not intended to be comparative across clinical trials.

- **Adult monotherapy (18+ years of age, SOLO 1 and SOLO 2)[2,8]:** The primary endpoint was the proportion of subjects with an IGA 0 (clear) or 1 (almost clear) and ≥2-point improvement at Week 16 (38% and 36% of DUPIXENT patients vs 10% and 9% with placebo in SOLO 1 and 2, respectively, *P*<0.001). Other endpoints included the proportion of subjects with ≥75% improvement in lesion extent and severity (EASI-75) at Week 16 (51% and 44% of DUPIXENT patients vs 15% and 12% with placebo in SOLO 1 and 2, respectively, *P*<0.001) and ≥4-point improvement in the Peak Pruritus NRS at Week 16 (41% and 36% of DUPIXENT patients vs 12% and 10% with placebo in SOLO 1 and 2, respectively, *P*<0.001)
- **Adolescents (12-17 years of age, AD-1526)[2,9]:** The primary endpoint was the proportion of subjects with an IGA 0 (clear) or 1 (almost clear) and ≥2-point improvement at Week 16 (24% of DUPIXENT patients vs 2% with placebo, *P*<0.001). Secondary endpoints included the proportion of subjects with ≥75% improvement in lesion extent and severity (EASI-75) at Week 16 (42% of DUPIXENT patients vs 8% with placebo, *P*<0.001) and ≥4-point improvement in the Peak Pruritus NRS at Week 16 (37% of DUPIXENT patients vs 5% with placebo, *P*<0.001)
- **Children (6-11 years of age, AD-1652)[2,10]:** The primary endpoint was the proportion of subjects with an IGA 0 (clear) or 1 (almost clear) at Week 16 (39% of patients ≥30 kg treated with DUPIXENT + TCS vs 10% with placebo + TCS, and 30% of patients <30 kg treated with DUPIXENT + TCS vs 13% with placebo + TCS). Other endpoints included the proportion of subjects with EASI-75 at Week 16 (75% of patients ≥30 kg treated with DUPIXENT + TCS vs 26% with placebo + TCS, and 75% of patients <30 kg treated with DUPIXENT + TCS vs 28% with placebo + TCS) and ≥4-point improvement in the Peak Pruritus NRS at Week 16 (61% of patients ≥30 kg treated with DUPIXENT + TCS vs 13% with placebo + TCS, and 54% of patients <30 kg treated with DUPIXENT + TCS vs 12% with placebo + TCS)

TRIAL DESIGNS: 917 adults in SOLO 1 and SOLO 2, 251 adolescents (12-17 years) in AD-1526, 162 infants to preschoolers (6 months to 5 years) in AD-1539 (16 weeks each), and 421 adults in CHRONOS (52 weeks) with moderate-to-severe atopic dermatitis and 367 children (6-11 years) in AD-1652 (16 weeks) with severe disease inadequately controlled with topical prescription therapies were randomized to DUPIXENT or placebo. All DUPIXENT-treated adults and adolescents ≥60 kg received 300 mg Q2W after a 600 mg loading dose, adolescents <60 kg and children ≥30 kg but <60 kg received 200 mg Q2W after a 400 mg loading dose, children 15 kg but <30 kg received 300 mg Q4W after a 600 mg loading dose; infants to preschoolers 15 kg but <30 kg received 300 mg Q4W, and infants to preschoolers 5 kg but <15 kg received 200 mg Q4W. In SOLO 1, SOLO 2, CHRONOS, AD-1526, and AD-1539 patients had an IGA score ≥3 on a scale of 0 to 4, an EASI score ≥16 on a scale of 0 to 72, and BSA involvement ≥10%. In AD-1652, patients had an IGA score of 4, an EASI score ≥21, and BSA involvement ≥15%. At baseline, 52% of adults, 46% of adolescents, and 23% of infants to preschoolers had an IGA score of 3 (moderate); 48% of adults, 54% of adolescents, and 77% of infants to preschoolers had an IGA of 4 (severe); mean EASI score was 33 for adults, 36 for adolescents, 37.9 for children, and 34.1 for infants to preschoolers; weekly averaged Peak Pruritus NRS was 7 for adults, 8 for adolescents, and 7.8 for children on a scale of 0 to 10; and weekly average of daily Worst Scratch/Itch NRS was 7.6 for infants to preschoolers on a scale of 0 to 10.[2,7]

BSA, body surface area; EASI, Eczema Area and Severity Index; NRS, numerical rating scale; Q2W, once every 2 weeks; Q4W, once every 4 weeks; TCS, topical corticosteroids.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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

Arthralgia: 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. 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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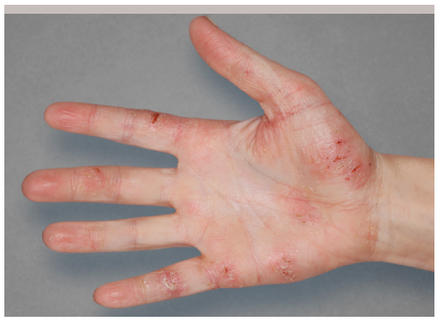
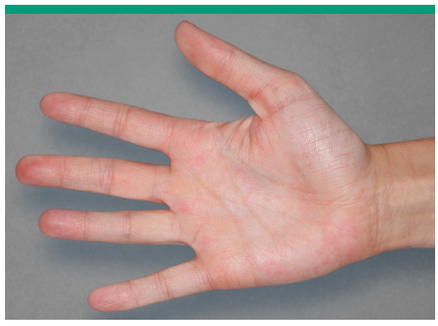
CHANGE YOU CAN SEE

ADULT PATIENT — 3-POINT IMPROVEMENT ON THE IGA SCALE

BASELINE: IGA 3 (moderate)



WEEK 16: IGA 0 (clear)

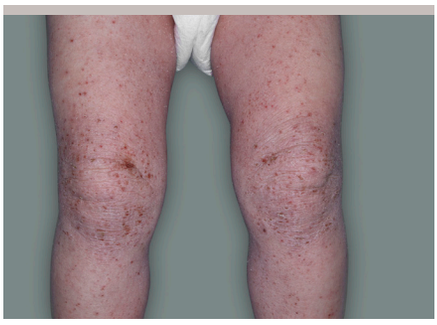


This adult patient was an actual patient treated with DUPIXENT. Not a clinical trial patient. Scoring was designated by the treating healthcare professional.

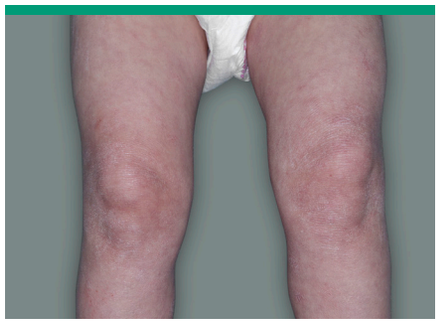
Because this was a real-world patient, other factors may have influenced their treatment results. Individual results may vary.

INFANT TO PRESCHOOLER PATIENT (2 YEARS OF AGE) — 2-POINT IMPROVEMENT ON THE IGA SCALE

BASELINE: IGA 4 (severe)



WEEK 16: IGA 2 (mild)



Actual patient in a phase 3 DUPIXENT trial (AD-1539) in infants to preschoolers (aged 6 months to 5 years).

Patient was prescribed concomitant low-potency TCS based on the clinical trial program. Individual results may vary.

A clinical responder was defined by achieving IGA 0 or 1 and, in adult trials, by also achieving a ≥2-point improvement from baseline.[2]

- IGA scale was defined as 0=clear, 1=almost clear, 2=mild, 3=moderate, and 4=severe[4]
- Infant to preschooler patient did not meet the primary endpoint in the clinical trial based on their IGA score at Week 16

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.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥1%) in patients with atopic dermatitis are injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, dry eye, and eosinophilia. The safety profile in pediatric patients through Week 16 was similar to that of adults with atopic dermatitis. In an open-label extension study, the long-term safety profile of DUPIXENT ± TCS in pediatric patients observed through Week 52 was consistent with that seen in adults with atopic dermatitis, with hand-foot-and-mouth disease and skin papilloma (incidence ≥2%) reported in patients 6 months to 5 years of age. These cases did not lead to study drug discontinuation.

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DEMONSTRATED LONG-TERM SAFETY PROFILE

The 52-Week safety profile of DUPIXENT + TCS in adults was generally consistent with the Week 16 adult safety profile[2]

Adverse reactions occurring in ≥1% of adult patients through Week 16[2]

Adverse reaction	DUPIXENT 300 mg Q2W monotherapy[a]		DUPIXENT 300 mg Q2W + TCS[b]	
	DUPIXENT[c] (n=529) %	Placebo (n=517) %	DUPIXENT + TCS[c] (n=110) %	Placebo + TCS (n=315) %
Injection site reaction	10	5	10	6
Conjunctivitis[d]	10	2	9	5
Blepharitis	<1	<1	5	1
Oral herpes	4	2	3	2
Keratitis[e]	<1	0	4	0
Eye pruritus	1	<1	2	1
Other herpes simplex virus infection[f]	2	1	1	<1
Dry eye	<1	0	2	<1

Treatment-emergent eosinophilia (≥5,000 cells/mcL) was reported in[2]:

- <3% of DUPIXENT-treated subjects and <0.5% of placebo-treated subjects (SOLO 1, SOLO 2, and AD-1021; DRI12544, QUEST, and VOYAGE; SINUS-24 and SINUS-52; PRIME and PRIME2)[g]
- 8% of DUPIXENT-treated subjects and 0% of placebo-treated subjects (AD-1539)

THE SAFETY PROFILE IN PEDIATRIC PATIENTS AGED 6+ MONTHS THROUGH WEEK 16 WAS SIMILAR TO THAT OF ADULTS WITH ATOPIC DERMATITIS[2]

[a] Pooled analysis of SOLO 1, SOLO 2, and AD-1021 (phase 2 dose-ranging study). [b] Analysis of CHRONOS in which subjects were on background TCS therapy. [c] DUPIXENT 600 mg at Week 0, followed by 300 mg every 2 weeks. [d] Conjunctivitis cluster includes conjunctivitis, allergic conjunctivitis, bacterial conjunctivitis, viral conjunctivitis, giant papillary conjunctivitis, eye irritation, and eye inflammation. [e] Keratitis cluster includes keratitis, ulcerative keratitis, allergic keratitis, atopic keratoconjunctivitis, and ophthalmic herpes simplex. [f] Other herpes simplex virus infection cluster includes herpes simplex, genital herpes, herpes simplex otitis externa, and herpes virus infection, but excludes eczema herpeticum. [g] DRI12544, QUEST, and VOYAGE are part of the asthma clinical trial program; SINUS-24 and SINUS-52 are part of the chronic rhinosinusitis with nasal polyposis clinical trial program; PRIME and PRIME2 are part of the prurigo nodularis clinical trial program.

IMPORTANT SAFETY INFORMATION

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.

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

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200mg · 300mg

IMPORTANT CONSIDERATIONS

NOT AN IMMUNOSUPPRESSANT OR A STEROID[2]

NO INITIAL LAB TESTING OR ONGOING LAB MONITORING

according to the Prescribing Information[2]

NO KNOWN DRUG-TO-DRUG INTERACTIONS[2]

- Not metabolized through the liver or excreted through the kidneys

NO BOXED WARNING[2]

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

- Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with DUPIXENT[2]
  - Avoid use of live vaccines during treatment with DUPIXENT

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.

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PARTNER WITH A SPECIALIST

AND CHANGE THEIR STORY TOGETHER

REVOLUTIONIZING THE TREATMENT OF ATOPIC DERMATITIS

6+ MONTHS OF AGE

Only FDA-approved therapy for uncontrolled moderate-to-severe atopic dermatitis patients as young as **6 months of age**

Real patients being treated with DUPIXENT. Individual results may vary.

#1 prescribed biologic by dermatologists and allergists in AD[4,a]

7 years since initial FDA approval in atopic dermatitis in adults[2,b]

Find an eczema specialist today. Visit DiscoverDupixent.com

[a] IQVIA SMART Portal Patient Insights as of [September 2024].
[b] FDA approved for uncontrolled moderate-to-severe atopic dermatitis since 2017 for adults, 2019 for adolescents (aged 12-17 years), 2020 for children (aged 6-11 years), and 2022 for infants to preschoolers (aged 6 months to 5 years).

INDICATION

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References: 1. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol*. 2024;90(2):E43-E56. **2.** DUPIXENT Prescribing Information. **3.** Simpson EL, Bruin-Weller M, Flohr C, et al. When does atopic dermatitis warrant systemic therapy? Recommendations from an expert panel of the International Eczema Council. *J Am Acad Dermatol*. 2017;77(4):623-633. **4.** Data on file, Regeneron Pharmaceuticals, Inc. **5.** Paul C, Griffiths CEM, Costanzo A, et al. Factors predicting quality of life impairment in adults with atopic dermatitis: results from a patient survey and machine learning analysis. *Dermatol Ther*. 2023;13(4):981-995. **6.** Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (LIBERTY AD CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. *Lancet*. 2017;389(10086):2287-2303. **7.** Paller AS, Simpson EL, Siegfried EC, et al. Dupilumab in children aged 6 months to younger than 6 years with uncontrolled atopic dermatitis: a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2022;400(10356):908-919. **8.** Simpson EL, Bieber T, Guttman-Yassky E, et al; SOLO 1 and SOLO 2 Investigators. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. *N Engl J Med*. 2016;375(24):2335-2348. **9.** Simpson EL, Paller AS, Siegfried EC, et al. Efficacy and safety of dupilumab in adolescents with uncontrolled moderate to severe atopic dermatitis: a phase 3 randomized clinical trial. *JAMA Dermatol*. 2020;156(1):44-56. **10.** Paller AS, Siegfried EC, Thaçi D, et al. Efficacy and safety of dupilumab with concomitant topical corticosteroids in children 6 to 11 years old with severe atopic dermatitis: a randomized, double-blinded, placebo-controlled phase 3 trial. *J Am Acad Dermatol*. 2020;83(5):1282-1293.

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