DUPIXENT®
(dupilumab) Injection
200mg · 300mg

"TOPICAL Rxs WEREN'T ENOUGH. WITH DUPIXENT HIS RASHES FADED, EVEN HIS FEET ARE LOOKING GREAT!"

- Tyler's parents

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

MEET TYLER

Age 14

Currently taking DUPIXENT—started in 2020

OUR STORY

Tyler has struggled to find control for his moderate-to-severe atopic dermatitis since infancy. Before DUPIXENT, despite using topical Rx therapies, nonstop itching and flares defined his childhood. We wanted his skin to get better with another treatment option.

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.

HIS SIGNS AND SYMPTOMS

- Itching throughout the day
- Extremely dry, scaly skin with severe rashes—sensitive areas such as his feet were a real problem
- He had oozing and crusting skin

HIS TREATMENT AND GOALS

- Topical prescription therapies worked for a while, but they stopped working and were damaging to his skin
- Chlorine baths and wet wraps were also ineffective
- We had to find another treatment that was appropriate for long-term use

THE DATA BEHIND THE STORY

DISEASE CONTROL DEMONSTRATED IN ADOLESCENTS (12-17 YEARS OF AGE) AT WEEK 16 IN 1 CLINICAL TRIAL[1,2]

37% DUPIXENT **VS** **5%** PLACEBO

adolescent patients who achieved **≥4-point reduction in Peak Pruritus NRS** at Week 16 in AD-1526 (*P*<0.001; secondary endpoint)

- **Itch reduction seen as early as Week 4** in some adolescent patients (**22%** with DUPIXENT [n=82] vs **5%** with placebo [n=84]; secondary endpoint; nominal *P*<0.001)[1]

42% DUPIXENT **VS** **8%** PLACEBO

adolescent patients who achieved **≥75% improvement in lesion extent and severity** at Week 16 in AD-1526 (*P*<0.001; secondary endpoint)

- **24%** of DUPIXENT adolescent patients achieved **clear or almost-clear skin** (IGA 0 or 1) vs **2%** with placebo at Week 16 in AD-1526 (primary endpoint; *P*<0.001)[1,2]

Definitive conclusions cannot be made for time points earlier than Week 16 as those data were not multiplicity-controlled and P value was nominal.

TRIAL DESIGNS: 917 adults in SOLO 1 and SOLO 2, 251 adolescents (12-17 years) in AD-1526 (16 weeks each), and 421 adults in CHRONOS (52 weeks) with moderate-to-severe atopic dermatitis inadequately controlled with topical Rx therapies were randomized to DUPIXENT or placebo. All patients in CHRONOS received concomitant TCS. All DUPIXENT-treated adults and adolescents ≥60 kg received 300 mg Q2W after a 600 mg loading dose, and adolescents <60 kg received 200 mg Q2W after a 400 mg loading dose. Patients had moderate-to-severe disease with 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%. At baseline, 52% of adults and 46% of adolescents had an IGA score of 3 (moderate), and 48% of adults and 54% of adolescents had an IGA of 4 (severe); mean EASI score was 33 for adults and 36 for adolescents; and weekly averaged Peak Pruritus NRS was 7 for adults and 8 for adolescents on a scale of 0 to 10.[2]

TRIAL ENDPOINTS: The primary endpoint was the proportion of subjects with an IGA of 0 (clear) or 1 (almost clear) and ≥2-point improvement at Week 16. Other endpoints included the proportion of subjects with EASI-75 at Week 16 and ≥4-point improvement in the Peak Pruritus NRS at Week 16.[2]

AD, atopic dermatitis; BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NRS, numerical rating scale; Q2W, once every 2 weeks; TCS, topical corticosteroids.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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.

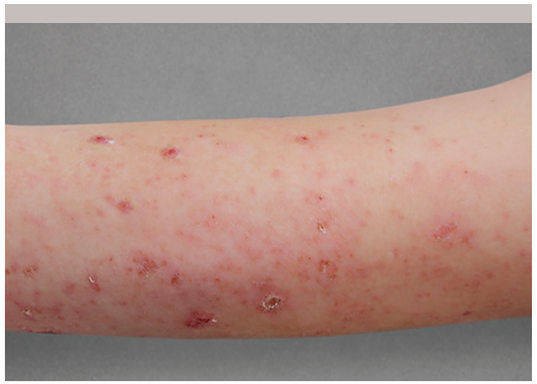
Risk Associated with Abrupt Reduction of Corticosteroid Dosage: Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of DUPIXENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a healthcare provider.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

VISIBLE RESULTS

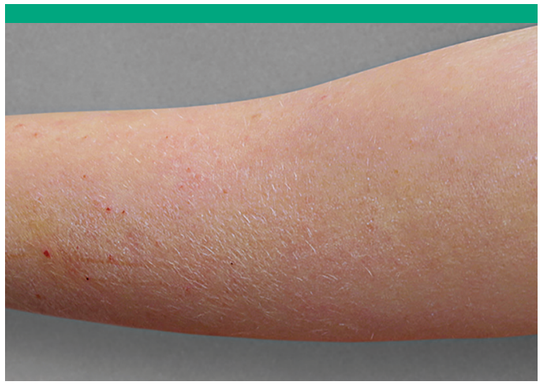
ADOLESCENT PATIENT—ACHIEVED A 2-POINT IMPROVEMENT IN IGA

Actual 12-year-old patient in the Phase 3 adolescent DUPIXENT trial. Patient had a baseline IGA of 4 and EASI of 31. Individual results may vary.

BASELINE: IGA 4 (severe)



WEEK 16: IGA 2 (mild)



A clinical responder was defined as a patient achieving IGA 0 or 1 and at least a 2-point improvement from baseline.[2]
- This adolescent patient did not meet the primary endpoint in the clinical trial based on their IGA score at Week 16

THE FIRST AND ONLY BIOLOGIC APPROVED TO TREAT UNCONTROLLED MODERATE-TO-SEVERE AD FROM INFANCY TO ADULTHOOD (6+ MONTHS OF AGE)

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.

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.

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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. The safety profile in adolescents through Week 16 (pivotal study) and Week 52 (open-label extension study) was consistent with that of adults with atopic dermatitis.[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)

[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.

IN AN OPEN-LABEL EXTENSION STUDY, THE LONG-TERM SAFETY PROFILE OF DUPIXENT IN ADOLESCENTS OBSERVED THROUGH WEEK 52 WAS CONSISTENT WITH THAT SEEN IN ADULTS WITH ATOPIC DERMATITIS[2]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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.

ATTRIBUTES AND CONSIDERATIONS

NOT AN IMMUNOSUPPRESSANT[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.

SELECT 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.

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.

References: 1. 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. **2.** DUPIXENT Prescribing Information. **3.** Data on file, Regeneron Pharmaceuticals, Inc.

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

WHEN TOPICAL Rx THERAPIES ARE NOT ENOUGH, DUPIXENT:

YOUR FIRST CHOICE

TO ADEQUATELY CONTROL THIS CHRONIC, SYSTEMIC DISEASE

Disease control demonstrated at Week 16[1,2]

- **37%** of adolescents treated with DUPIXENT **achieved ≥4-point reduction in Peak Pruritus NRS** vs **5%** with placebo in AD-1526 (secondary endpoint; *P*<0.001)
- **24%** of DUPIXENT patients **achieved clear or almost-clear skin (IGA 0 or 1)** vs **2%** with placebo in AD-1526 (primary endpoint; *P*<0.001)

NOT AN IMMUNOSUPPRESSANT[2]

52 WEEKS

A demonstrated safety profile in adolescent patients (12-17 years)[2]

- **Most common adverse reactions (incidence ≥1%) are** injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, dry eye, and eosinophilia
- The 52-week safety profile of DUPIXENT + TCS in adults was generally consistent with the Week 16 adult safety profile
- The safety profile in adolescents 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 in adolescents observed through Week 52 was consistent with that seen in adults with atopic dermatitis

NO REQUIREMENT FOR INITIAL LAB TESTING OR ONGOING LAB MONITORING, according to the Prescribing Information[2]

#1 prescribed biologic by dermatologists[3,a]

6 YEARS

since initial FDA approval in AD[2,b]

NO BOXED WARNING[2]

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

IMPORTANT SAFETY INFORMATION

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[a] IQVIA NBRx data as of July 2023.
[b] FDA approved 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) with uncontrolled moderate-to-severe atopic dermatitis.

SEE HOW OTHER PATIENTS LIKE TYLER ACHIEVE CHANGE IN ITCH AND SKIN LESIONS WITH DUPIXENT

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