DUPIXENT®
(dupilumab) Injection
200mg · 300mg

“HOW DO YOU GET A BABY TO STOP ITCHING? THE TOPICAL Rxs WEREN’T ENOUGH. WHAT A DIFFERENCE WITH DUPIXENT.”

- Sienna’s parents

Not an actual patient.

MEET SIENNA

Age 4

OUR STORY

Topical Rxs were not enough and needed to be applied throughout the day. We saw a dermatologist and then an allergist, who prescribed DUPIXENT for her uncontrolled moderate-to-severe atopic dermatitis. Her itch has improved.

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.

HER SIGNS AND SYMPTOMS

- Uncontrollable scratching on face and neck
- Recurring lesions on legs
- Scaly patches on her wrists and arms
- Constant intense itch
- Also suffers from comorbid asthma currently managed with asthma medication

HER TREATMENT AND GOALS

- Applying topical Rxs frequently during the day was challenging on a young child
- Oatmeal baths, wet wraps, and other home remedies were not enough
- Needed another treatment approved for her young age

THE DATA BEHIND THE STORY

DISEASE CONTROL IN INFANTS TO PRESCHOOLERS (AGED 6 MONTHS TO 5 YEARS) DEMONSTRATED AT WEEK 16 IN 1 CLINICAL TRIAL[1,2]

48% DUPIXENT + TCS **VS** **9%** PLACEBO + TCS

infants to preschoolers who achieved **≥4-point reduction in Worst Scratch/Itch NRS** at Week 16 in AD-1539 (*P*<0.0001; secondary endpoint)

- **Reduction in itch after the first dose at Week 3** in some patients (**22%** with DUPIXENT + TCS [n=83] vs **4%** with placebo + TCS [n=79])[3]

53% DUPIXENT + TCS **VS** **11%** PLACEBO + TCS

infants to preschoolers who achieved **≥75% improvement in lesion extent and severity** at Week 16 in AD-1539 (*P*<0.0001; secondary endpoint)

- **28%** of DUPIXENT + TCS patients achieved **clear or almost-clear skin** (IGA 0 or 1) vs **4%** with placebo + TCS at Week 16 in AD-1539 (primary endpoint; *P*<0.0001)[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 DESIGN: 162 infants to preschoolers (6 months to 5 years) in AD-1539 (16 weeks) with moderate-to-severe atopic dermatitis inadequately controlled with topical prescription therapies were randomized to DUPIXENT + TCS or placebo + TCS. Patients 15 kg but <30 kg received 300 mg Q4W. Patients 5 kg but <15 kg received 200 mg Q4W. 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 of ≥10%. At baseline, 23% of infants to preschoolers had an IGA score of 3 (moderate), 77% had an IGA of 4 (severe), mean EASI score was 34.1, and weekly average of daily Worst Scratch/Itch NRS was 7.6 on a scale of 0 to 10.[1,2]

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

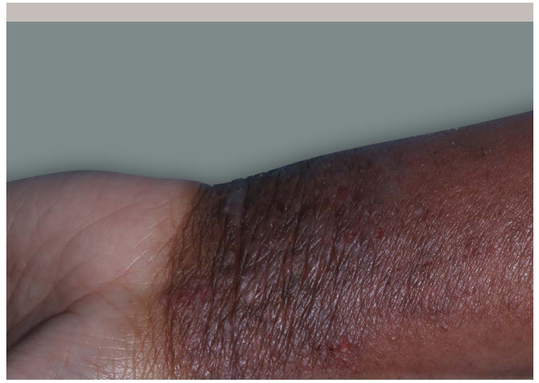
AD, atopic dermatitis; BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NRS, numerical rating scale; Q4W, once every 4 weeks; TCS, topical corticosteroids.

VISIBLE RESULTS

4-YEAR-OLD PATIENT—ACHIEVED A 3-POINT IMPROVEMENT IN IGA

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. Patient was considered a clinical responder. Individual results may vary.

BASELINE: IGA 4 (severe)



WEEK 16: IGA 1 (almost clear)

A clinical responder was defined by achieving IGA 0 or 1.[1]

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)

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.

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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 SAFETY PROFILE

The safety profile in infants to preschoolers through Week 16 was similar to that of adults with atopic dermatitis[1]

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

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[1]:

- <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.

DUPIXENT vs placebo: rates of treatment discontinuation and skin infection

	Week 16, AD-1539
Comparable rate of **discontinuations due to adverse events** vs placebo[2]	1% (DUPIXENT + TCS) vs 1% (Placebo + TCS)
Numerically fewer patients developed **skin infections** vs placebo[2,h]	12% (DUPIXENT + TCS) vs 24% (Placebo + TCS)

- **Patients should discontinue DUPIXENT if a clinically significant hypersensitivity reaction occurs or until a parasitic (helminth) infection resolves in a patient who does not respond to anti-helminth treatment[1]**

[h] Data reflect adjudicated nonherpetic skin infections through Week 16.

THE FIRST AND ONLY BIOLOGIC WITH A DEMONSTRATED SAFETY PROFILE FOR INFANTS TO PRESCHOOLERS (6 MONTHS TO 5 YEARS OF AGE) IN ATOPIC DERMATITIS

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 in patients treated with DUPIXENT.

ATTRIBUTES AND CONSIDERATIONS

NOT AN IMMUNOSUPPRESSANT[1]

NO INITIAL LAB TESTING OR ONGOING LAB MONITORING

according to the Prescribing Information[1]

NO KNOWN DRUG-TO-DRUG INTERACTIONS[1]

- Not metabolized through the liver or excreted through the kidneys

NO BOXED WARNING[1]

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

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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IMPORTANT SAFETY INFORMATION

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.

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

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WHEN TOPICAL Rx THERAPIES ARE NOT ENOUGH, DUPIXENT:

YOUR FIRST CHOICE

TO ADEQUATELY CONTROL THIS CHRONIC, SYSTEMIC DISEASE

Significant itch reduction and skin clearance[1,2]

- **48%** of infants to preschoolers treated with DUPIXENT + TCS (n=83) **achieved ≥4-point reduction in Worst Scratch/Itch NRS** vs **9%** with placebo + TCS (n=79) at Week 16 in AD-1539 (*P*<0.0001; secondary endpoint)
- **28%** of infants to preschoolers treated with DUPIXENT + TCS (n=83) **achieved clear or almost-clear skin (IGA 0 or 1)** vs **4%** with placebo + TCS (n=79) at Week 16 in AD-1539 (*P*<0.0001; primary endpoint)

NOT AN IMMUNOSUPPRESSANT[1]

52 WEEKS

A demonstrated safety profile[1]

- **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 infants to preschoolers through Week 16 (in a pivotal trial) and Week 52 (in an open-label extension trial, AD-1434) was similar to that of adults with atopic dermatitis
  - In AD-1434, hand-foot-and-mouth disease and skin papilloma (incidence ≥2%) was reported in patients 6 months to 5 years of age. These cases did not lead to study drug discontinuation

NO REQUIREMENT FOR INITIAL LAB TESTING OR ONGOING LAB MONITORING, according to the Prescribing Information[1]

#1 prescribed biologic by dermatologists[3,a]

6 YEARS

since initial FDA approval in AD[1,b]

NO BOXED WARNING[1]

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

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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[a] IQVIA NBRx data as of [December 2022].
[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 SIENNA ACHIEVE CHANGE IN ITCH AND SKIN LESIONS WITH DUPIXENT

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