DUPIXENT®
(dupilumab) Injection
200mg · 300mg

"BEFORE DUPIXENT, HARPER'S HANDS WERE A BIG PROBLEM. TOPICAL Rxs JUST WEREN'T ENOUGH."

- Harper's parents

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

MEET HARPER

Age 8

Currently taking DUPIXENT

OUR STORY

After struggling with moderate-to-severe atopic dermatitis since early childhood, Harper was referred to a specialist by her primary care doctor when topical prescription therapies were not enough. We saw an allergist and a dermatologist. Now on DUPIXENT, Harper has less itching.

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

- Constant burning and itching that never went away
- Scratching throughout the night
- Puffy swollen eyes during a flare
- Her fingers and toes would bleed regularly

HER TREATMENT AND GOALS

- Treatments from oral and topical prescriptions to bleach baths and light therapy—all were unsuccessful
- We needed a treatment that could help reduce her itch and clear her skin

THE DATA BEHIND THE STORY

DISEASE CONTROL DEMONSTRATED AT WEEK 16 IN A CLINICAL TRIAL OF CHILDREN (6-11 YEARS OF AGE) WITH SEVERE DISEASE[1,2,a-c]

61% vs **13%**

DUPIXENT + TCS (n=59) | **PLACEBO + TCS (n=62)**

of children (≥30 kg; 200 mg Q2W)[d,e]

54% vs **12%**

DUPIXENT + TCS (n=61) | **PLACEBO + TCS (n=61)**

of children (<30 kg; 300 mg Q4W)[d,f] achieved **≥4-point reduction in Peak Pruritus NRS** at Week 16 in AD-1652 (secondary endpoint)

75% vs **26%**

DUPIXENT + TCS (n=59) | **PLACEBO + TCS (n=62)**

of children (≥30 kg; 200 mg Q2W)[d,e]

75% vs **28%**

DUPIXENT + TCS (n=61) | **PLACEBO + TCS (n=61)**

of children (<30 kg; 300 mg Q4W)[d,f] achieved **≥75% improvement in lesion extent and severity (EASI-75)** at Week 16 in AD-1652 (secondary endpoint)

- At **Week 16** in AD-1652, **39%** of children treated with DUPIXENT + TCS (≥30 kg; 200 mg Q2W) achieved **clear or almost-clear skin (IGA 0 or 1)** vs **10%** with placebo + TCS (primary endpoint); **30%** vs **13%** of children <30 kg (300 mg Q4W + TCS vs placebo + TCS; primary endpoint)[1,2]

[a] Full Analysis Set includes all subjects randomized.
[b] In the primary analyses of the efficacy endpoints, subjects who received rescue treatment or with missing data were considered nonresponders.
[c] The study population in AD-1652 included children with only severe atopic dermatitis.
[d] A 600 mg loading dose was given as 2 injections of 300 mg, and a 400 mg loading dose was given as 2 injections of 200 mg.
[e] At Day 1, subjects (baseline weight ≥30 kg) received 400 mg of DUPIXENT.
[f] At Day 1, subjects (baseline weight <30 kg) received 600 mg of DUPIXENT.

TRIAL DESIGN: 367 children (6-11 years of age) in AD-1652 (16 weeks) with severe atopic dermatitis inadequately controlled with topical prescription therapies were randomized to DUPIXENT + TCS or placebo + TCS. Patients ≥30 kg but <60 kg received 200 mg Q2W after a 400 mg loading dose. Patients 15 kg but <30 kg received 300 mg Q4W after a 600 mg loading dose. Patients had an IGA score of 4, an EASI score ≥21, and BSA involvement ≥15%. Mean EASI score was 37.9 and weekly averaged Peak Pruritus NRS was 7.8 on a scale of 0 to 10.[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 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; Q4W, once every 4 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.

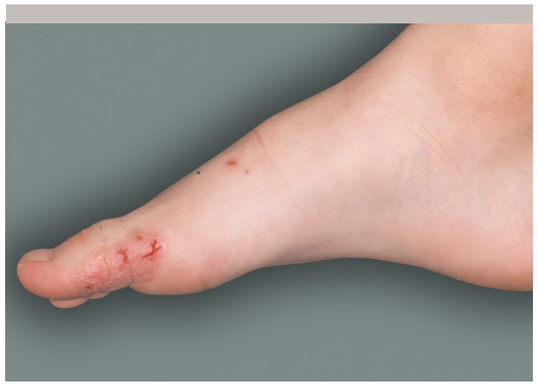
Risk Associated with Abrupt Reduction of Corticosteroid Dosage: Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of DUPIXENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a healthcare provider.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

VISIBLE RESULTS

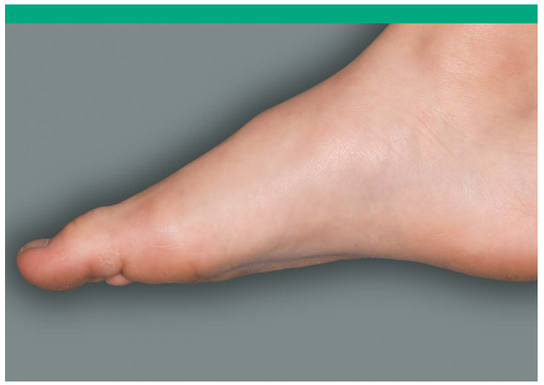
9-YEAR-OLD PATIENT ACHIEVED A 3-POINT IMPROVEMENT IN IGA[3]

Actual patient in a Phase 3 pediatric DUPIXENT trial (AD-1652). Patient was prescribed concomitant 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 as a patient achieving IGA 0 or 1.[2]

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 children 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 CHILDREN 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 in patients treated 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. 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. **2.** DUPIXENT Prescribing Information. **3.** Shumel B, Rossi AB. Dupilumab treatment provides multidimensional improvement of signs, symptoms, and quality of life in children with severe atopic dermatitis: a pictorial guide. *Dermatologist.* 2020;28(8):42-46. **4.** 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

Clinically meaningful results shown in children (6-11 years)[1,2]

- **61%** of children treated with DUPIXENT + TCS (≥30 kg; 200 mg Q2W; n=59) achieved **≥4-point reduction in Peak Pruritus NRS** vs **13%** with placebo + TCS at Week 16 in AD-1652 (n=62; secondary endpoint); **54%** treated with DUPIXENT + TCS (<30 kg; 300 mg Q4W; n=61) vs **12%** with placebo + TCS (n=61; secondary endpoint)
- **39%** of children treated with DUPIXENT + TCS (≥30 kg; 200 mg Q2W; n=59) achieved **clear or almost-clear skin (IGA 0 or 1)** vs **10%** with placebo + TCS at Week 16 in AD-1652 (n=62; primary endpoint); **30%** treated with DUPIXENT + TCS (<30 kg; 300 mg Q4W; n=61) vs **13%** with placebo + TCS (n=61; primary endpoint)

52 WEEKS — Demonstrated safety profile in children (6-11 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 children 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 children observed through Week 52 was consistent with that seen in adults with atopic dermatitis

NOT AN IMMUNOSUPPRESSANT[2]

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

NO BOXED WARNING[2]

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

#1 prescribed biologic by dermatologists[4,a]

6 YEARS
since initial FDA approval in AD[2,b]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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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 HARPER ACHIEVE CHANGE IN ITCH AND SKIN LESIONS WITH DUPIXENT

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