DUPIXENT®
(dupilumab) Injection
200mg · 300mg

"I NEEDED A LONG-TERM OPTION. MY ARMS WERE CONSTANTLY ITCHING. TOPICAL Rxs DIDN'T HELP. DUPIXENT DOES."

- Arsalan

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

MEET ARSALAN

Age 29

Currently taking DUPIXENT

MY STORY

I've been seeing specialists for my moderate-to-severe atopic dermatitis since I was 6 years old. It was uncontrolled on topical Rx therapies. Itching was the worst, but since DUPIXENT, it's more under control. My skin has noticeably cleared up.

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.

MY SIGNS AND SYMPTOMS

- Flare-ups started as red patches of itchy skin
- Red patches would transition into more white, discolored patches that were still itchy
- I would get patches all over my body and my skin would crack and bleed

MY TREATMENT AND GOALS

- Tried a number of different holistic remedies
- Prescription allergy medications and topical corticosteroids
- Treatments worked for a while, but they stopped working—I needed an option that I could take continuously and would last

THE DATA BEHIND THE STORY

RAPID ITCH REDUCTION AND SUSTAINED DISEASE CONTROL DEMONSTRATED AT 52 WEEKS[1-3]

51% DUPIXENT + TCS vs **13%** PLACEBO + TCS

adult patients who achieved **≥4-point reduction in Peak Pruritus NRS** at Week 52 in CHRONOS (*P*<0.0001; secondary endpoint)

- **Rapid itch reduction seen as early as Week 2** in some patients (**≈18%** with DUPIXENT + TCS [n=102] vs **8%** with placebo + TCS [n=299]; secondary endpoint; *P*=0.0062)[3]

65% DUPIXENT + TCS vs **22%** PLACEBO + TCS

adult patients who sustained **≥75% improvement in lesion extent and severity** at Week 52 in CHRONOS (*P*<0.0001; secondary endpoint)

- **39%** of DUPIXENT + TCS patients achieved **clear or almost-clear skin** (IGA 0 or 1) vs **12%** with placebo + TCS at Week 16 in CHRONOS (primary endpoint; *P*<0.0001)[1,2]

TRIAL DESIGNS AND RESULTS: 917 adults in SOLO 1 and SOLO 2 (16 weeks each) and 421 adults in CHRONOS (52 weeks) with moderate-to-severe atopic dermatitis inadequately controlled with topical prescription therapies were randomized to DUPIXENT or placebo. All patients in CHRONOS were treated with concomitant TCS. All patients who received DUPIXENT were given 300 mg Q2W after a 600 mg loading dose. 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, 52% had an IGA score of 3 (moderate), 48% had an IGA of 4 (severe), mean EASI score was 33, and weekly averaged Peak Pruritus NRS was 7 on a scale of 0 to 10.[2]

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 patients treated with DUPIXENT vs 10% and 9% with placebo in SOLO 1 and SOLO 2, respectively, *P*<0.001; 39% of patients treated with DUPIXENT + TCS vs 12% with placebo + TCS in CHRONOS, *P*<0.0001). Other endpoints included the proportion of subjects with EASI-75 at Week 16 (51% and 44% of patients treated with DUPIXENT vs 15% and 12% with placebo in SOLO 1 and SOLO 2, respectively, *P*<0.001; 69% of patients treated with DUPIXENT + TCS vs 23% with placebo + TCS in CHRONOS, *P*<0.0001) and ≥4-point improvement in the Peak Pruritus NRS at Week 16 (41% and 36% of patients treated with DUPIXENT vs 12% and 10% with placebo in SOLO 1 and SOLO 2, respectively, *P*<0.001; 59% of patients treated with DUPIXENT + TCS vs 20% with placebo + TCS in CHRONOS, *P*<0.0001).[1,2,4]

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.

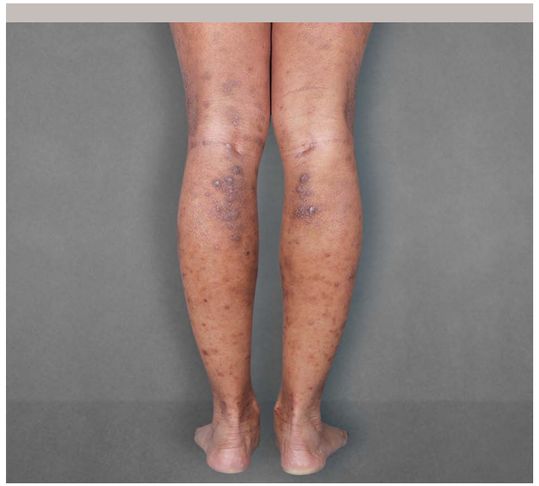
Risk Associated with Abrupt Reduction of Corticosteroid Dosage: Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of DUPIXENT. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a healthcare provider.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

VISIBLE RESULTS

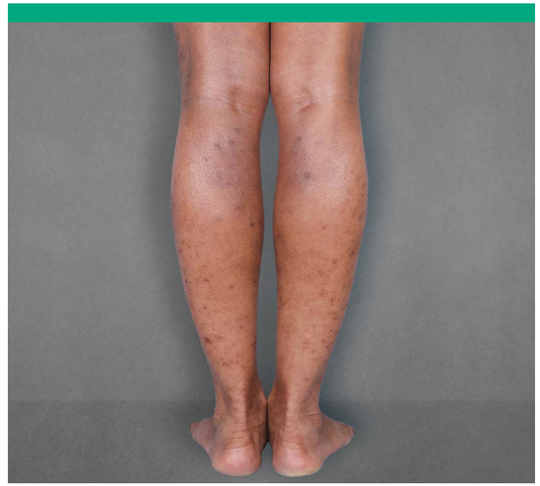
ADULT PATIENT—ACHIEVED A 4-POINT IMPROVEMENT IN IGA

This adult patient was an actual patient treated with DUPIXENT. Not a clinical trial patient. Note that this patient was on concomitant therapies, such as TCS, phototherapy, etc, at the prescribing physician's discretion. Scoring was designated by the treating physician. Because this patient was a real-world patient, other factors may have influenced treatment results, and individual results may vary.

BASELINE: IGA 4 (severe)



WEEK 16: IGA 0 (clear)



A clinical responder was defined as a patient achieving IGA 0 or 1 and at least a 2-point improvement from baseline.[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.

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.

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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)

[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

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.

IMPORTANT CONSIDERATIONS

SAFETY FINDINGS OF DUPIXENT OPEN-LABEL EXTENSION (OLE) STUDY IN ADULTS FOR ≈4 YEARS (AD-1225)[2,5]

- The long-term safety profile observed in this trial up to 244 weeks (≈4 years) was generally consistent with that observed in 16- and 52-week controlled studies
- 3.7% of patients discontinued due to treatment emergent adverse events in the OLE study
  - **Study description:** The safety data in this open-label extension study reflect exposure to DUPIXENT in 2677 subjects, including 2207 exposed for up to 52 weeks, 1065 exposed for up to 100 weeks, 557 exposed for up to 148 weeks, 352 exposed for up to 204 weeks, and 202 exposed for up to 244 weeks. 2677 patients were treated with 300 mg QW for up to 204 weeks. 226 of these patients transitioned to 300 mg Q2W with mean exposure of 46.7 ± 7.4 weeks at this dose.

    In DUPIXENT clinical trials, DUPIXENT 300 mg QW did not demonstrate additional treatment benefit over DUPIXENT 300 mg Q2W
  - **Limitations of this OLE study included, but were not limited to:** the open-label design, the absence of a placebo arm, treatment interruptions because of protocol amendments, the smaller subset of patients who received Q2W dosing, the smaller subset of patients who transitioned from QW to Q2W dosing, and the smaller sample size at later timepoints, which was primarily because of study termination by the sponsor following regulatory approval of dupilumab in the enrollment country

DUPIXENT 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.

QW, once weekly.

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.

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

References: 1. 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. **2.** DUPIXENT Prescribing Information. **3.** Data on file, Regeneron Pharmaceuticals, Inc. **4.** 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. **5.** Beck LA, Deleuran M, Bissonnette R, et al. Dupilumab provides acceptable safety and sustained efficacy for up to 4 years in an open-label study of adults with moderate-to-severe atopic dermatitis. *Am J Clin Dermatol*. 2022;23(3):393-408.

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WHEN TOPICAL Rx THERAPIES ARE NOT ENOUGH, DUPIXENT:

YOUR FIRST CHOICE

TO ADEQUATELY CONTROL THIS CHRONIC, SYSTEMIC DISEASE

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

In some adults treated with DUPIXENT + TCS

- **Rapid itch reduction after the first dose (as measured at Week 2); Week 16 results sustained at 1 year[1,3]**
- **≥75% improvement in lesion extent and severity (EASI-75) at Week 16 sustained at 1 year[1,2]**
- **Clear or almost-clear skin (IGA 0 or 1) at Week 16[1,2]**

NOT AN IMMUNOSUPPRESSANT[2]

52 WEEKS

A demonstrated long-term safety profile in adult patients[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

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

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 ARSALAN ACHIEVE CHANGE IN ITCH AND SKIN LESIONS WITH DUPIXENT

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