ARE YOU & YOUR PATIENTS AGED 6+ YEARS TRAPPED IN "FLARE THEN TREAT" CYCLES? IF FLARES ARE UNRELENTING DESPITE TOPICAL Rx USE...

IT MIGHT BE TIME TO REFER

Visit **DiscoverDupixent.com** to learn more

INDICATION

DUPIXENT is indicated for the treatment of patients aged 6 years 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.

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

AD, atopic dermatitis.

DUPIXENT® (dupilumab) Injection
200mg · 300mg
REVOLUTIONIZING AD

PARTNER IN CARE

PARTNER IN RELIEF

WHEN TOPICAL Rx THERAPIES ARE NOT ENOUGH

PATIENTS MAY BENEFIT FROM A DIFFERENT APPROACH THAT'S REVOLUTIONIZING ATOPIC DERMATITIS

Atopic dermatitis is a chronic, systemic disease driven in part by persistent underlying inflammation[1,2]

- Even when patients are not in a flare, they continue to experience underlying inflammation[1,2]
- Systemic treatment may offer effective treatment for uncontrolled moderate-to-severe atopic dermatitis[2,3]

DUPIXENT is a biologic that is prescribed by an eczema specialist, such as a dermatologist or allergist

- Unlike topical and oral corticosteroids, DUPIXENT targets a source of underlying inflammation to proactively treat atopic dermatitis[2,4,5]
- Topical Rx therapies may not be adequate enough to treat moderate-to-severe atopic dermatitis[4]
- DUPIXENT is a breakthrough therapy in the management of atopic dermatitis

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions, including generalized urticaria, rash, erythema nodosum, anaphylaxis and serum sickness or serum sickness-like reactions, were reported in <1% of subjects who received DUPIXENT in clinical trials. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Conjunctivitis and Keratitis: Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received DUPIXENT. Conjunctivitis was the most frequently reported eye disorder. Most subjects with conjunctivitis or keratitis recovered or were recovering during the treatment period. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

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WHEN TOPICAL Rx THERAPIES ARE NOT ENOUGH, CONSIDER REFERRING TO A DERMATOLOGIST OR ALLERGIST TODAY TO SEE WHAT'S POSSIBLE WITH DUPIXENT

Proven efficacy in adolescents (12-17 years) and children (6-11 years) with uncontrolled moderate-to-severe atopic dermatitis

SIGNIFICANT ITCH REDUCTION[5-7,a,b]

IN ADOLESCENTS:

- **37% of adolescent patients** treated with DUPIXENT (n=82) achieved **≥4-point reduction in Peak Pruritus NRS** at Week 16 in Trial 6 vs **5%** with placebo (n=85; secondary endpoint; *P*<0.001)

IN CHILDREN:

- **61% of children** treated with DUPIXENT + TCS (≥30 kg; 200 mg Q2W; n=59)[c,d] achieved **≥4-point reduction in Peak Pruritus NRS** vs **13%** with placebo + TCS at Week 16 in Trial 8 (n=62; secondary endpoint); **54%** treated with DUPIXENT + TCS (<30 kg; 300 mg Q4W; n=61)[c,e] vs **12%** with placebo + TCS (n=61; secondary endpoint)

SIGNIFICANT SKIN CLEARANCE[5-7,a,b]

IN ADOLESCENTS:

- **24% of adolescent patients** treated with DUPIXENT (n=82) achieved **clear or almost-clear skin** (IGA 0 or 1) at Week 16 vs **2%** with placebo (n=85; primary endpoint; *P*<0.001)

IN CHILDREN:

- **39% of children** treated with DUPIXENT + TCS (≥30 kg; 200 mg Q2W; n=59)[c,d] achieved **clear or almost-clear skin** (IGA 0 or 1) vs **10%** with placebo + TCS at Week 16 in Trial 8 (n=62; primary endpoint); **30%** treated with DUPIXENT + TCS (<30 kg; 300 mg Q4W; n=61)[c,e] vs **13%** with placebo + TCS (n=61; primary endpoint)

An established long-term safety profile across patients 6 years and older

52 WEEKS DEMONSTRATED SAFETY PROFILE THROUGH 52 WEEKS[5]

- Most common adverse reactions (incidence ≥1% at Week 16) in adult patients with atopic dermatitis are injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, and dry eye
- The safety profile in children and 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 and children observed through Week 52 was consistent with that seen in adults with atopic dermatitis

TRIAL DESIGNS AND RESULTS: A total of 917 adults in Trials 1 and 2, 251 adolescents in Trial 6, 367 children (6-11 years of age) in Trial 8 (16 weeks each), and 421 adults in Trial 3 (52 weeks) with moderate-to-severe atopic dermatitis inadequately controlled with topical prescription therapies were randomized to DUPIXENT or placebo. All patients in Trials 3 and 8 received concomitant TCS. All 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. In Trials 1, 2, 3, and 6, patients had moderate-to-severe disease, with an IGA score ≥3 (overall lesion severity scale of 0 to 4), an EASI score ≥16 on a scale of 0 to 72, and BSA involvement ≥10%. In Trial 8, patients had an IGA score of 4 (severe), an EASI score ≥21, and BSA involvement ≥15%. At baseline, 52% of adults and 46% of adolescents had an IGA score of 3 (moderate), 48% of adults and 54% of adolescents had an IGA of 4 (severe); mean EASI score was 33 for adults, 36 for adolescents, and 37.9 for children; weekly averaged Peak Pruritus NRS was 7 for adults, 8 for adolescents, and 7.8 for children, on a scale of 0 to 10.[5]

The primary endpoint in Trials 1, 2, 3, and 6 was change from baseline in the proportion of subjects with an IGA 0 (clear) or 1 (almost clear) and ≥2-point improvement at Week 16 (38% and 36% of adults treated with DUPIXENT vs 10% and 9% with placebo in Trials 1 and 2, respectively, *P*<0.001; 39% of adults treated with DUPIXENT + TCS vs 12% with placebo + TCS in Trial 3, *P*<0.0001). In Trial 8, the primary endpoint was change from baseline in the proportion of subjects with an IGA 0 or 1 at Week 16. Other endpoints included change from baseline in the proportion of subjects with EASI-75 at Week 16 (improvement of ≥75%; 51% and 44% of adults treated with DUPIXENT vs 15% and 12% with placebo in Trials 1 and 2, respectively, *P*<0.001; 69% of adults treated with DUPIXENT + TCS vs 23% with placebo + TCS in Trial 3, *P*<0.0001; 75% of children ≥30 kg treated with DUPIXENT + TCS vs 26% with placebo + TCS, and 75% of children <30 kg treated with DUPIXENT + TCS vs 28% with placebo + TCS in Trial 8); and itch reduction defined by ≥4-point improvement in the Peak Pruritus NRS at Week 16 (41% and 36% of adults treated with DUPIXENT vs 12% and 10% with placebo in Trials 1 and 2, respectively, *P*<0.001; 59% of adults treated with DUPIXENT + TCS vs 20% with placebo + TCS in Trial 3, *P*<0.0001).[5-9]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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

NOT AN IMMUNOSUPPRESSANT OR A STEROID[5]

NO REQUIREMENT FOR INITIAL LAB TESTING OR ONGOING LAB MONITORING ACCORDING TO THE PRESCRIBING INFORMATION[5]

AFTER AN INITIAL LOADING DOSE, WEIGHT-TIERED DOSING AND FREQUENCY IN CHILDREN AND ADOLESCENTS[5,c]

- At-home administration

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

[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] 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.
[d] At Day 1, subjects (baseline weight ≥30 kg) received 400 mg of DUPIXENT.
[e] At Day 1, subjects (baseline weight <30 kg) received 600 mg of DUPIXENT.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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

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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109,000 PATIENTS
have filled at least 1 DUPIXENT prescription[6,a,b]

[a] IQVIA National Prescription Audit (NPA) data as of May 2020.
[b] New adult and adolescent patients with atopic dermatitis.

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IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥1% at Week 16) in adult patients with atopic dermatitis are injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, and dry eye. The safety profile in children and 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 and children observed through Week 52 was consistent with that seen in adults with atopic dermatitis.

DRUG INTERACTIONS: Avoid use of live vaccines in patients treated with DUPIXENT.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to DUPIXENT during pregnancy. Healthcare providers and patients may call 1-877-311-8972 or go to https://mothertobaby.org/ongoing-study/dupixent/ to enroll in or obtain information about the registry. 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.

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References: 1. Leung DYM, Boguniewicz M, Howell MD, Nomura I, Hamid QA. New insights into atopic dermatitis. *J Clin Invest.* 2004;113(5):651-657. **2.** Gandhi NA, Bennett BL, Graham NMH, Pirozzi G, Stahl N, Yancopoulos GD. Targeting key proximal drivers of type 2 inflammation in disease. *Nat Rev Drug Discov.* 2016;15(1):35-50. **3.** Boguniewicz M, Fonacier L, Guttman-Yassky E, Ong PY, Silverberg J, Farrar JR. Atopic dermatitis yardstick: practical recommendations for an evolving therapeutic landscape. *Ann Allergy Asthma Immunol.* 2019;120(1):10-22.e2. doi:10.1016/j.anai.2018.07.004 **4.** Wei W, Anderson P, Gadkari A, et al. Extent and consequences of inadequate disease control among adults with a history of moderate to severe atopic dermatitis. *J Dermatol.* 2018;45(2):150-157. **5.** DUPIXENT Prescribing Information. **6.** Data on file, Regeneron Pharmaceuticals, Inc. **7.** 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. **8.** 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. **9.** 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.

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REGENERON

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