



THE FIRST AND ONLY BIOLOGIC APPROVED FOR PATIENTS FROM INFANCY TO ADULTHOOD WITH UNCONTROLLED MODERATE-TO-SEVERE ATOPIC DERMATITIS

#### **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.

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



IN MODERATE-TO-SEVERE ATOPIC DERMATITIS

WHEN TOPICAL RX THERAPIES ARE NOT

ENOUGH, IT MAY BE TIME TO REFER TO A SPECIALIST

> 6+ Months Of age



CONSIDER REFERRING TODAY Real adolescent and child patients being treated with DUPIXENT. Individual results may vary. The infant to preschooler (6 months to 5 years of age) is not an actual patient.



STUCK IN A CYCLE OF FLARE, TREAT, REPEAT?



REFER TO A SPECIALIST



HELP CHANGE THE STORY

## 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.

**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.

#### **WHO TO REFER**

Consider referring your patients if they:

- Have tried a variety of topical prescription therapies for moderate-to-severe atopic dermatitis and are still uncontrolled<sup>1</sup>
- Suffer from inadequate control of pruritus<sup>2</sup>
- Have ≥10% of their body covered with lesions and/or may involve problem areas, such as the face, hands, and feet<sup>2</sup>
- Have moderate-to-severe erythema and moderate-to-severe papulation/infiltration (IGA 3 or 4)<sup>3</sup>

### TAKE ANOTHER APPROACH

DUPIXENT targets a source of underlying inflammation to proactively treat atopic dermatitis—a chronic, systemic disease driven in part by persistent underlying type 2 inflammation.<sup>1,4,5</sup>

The mechanism of dupilumab action has not been definitively established.<sup>1</sup>

Even when patients are not in a flare, they continue to have underlying inflammation—systemic treatment may be needed to help manage this disease.<sup>4-6</sup>

# IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS (cont'd)

**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.

**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 during treatment with DUPIXENT.

Please see additional Important Safety Information throughout and click <a href="here">here</a> for full Prescribing Information.



# SEE WHAT DUPIXENT CAN DO

# PROVEN EFFICACY IN PEDIATRIC PATIENTS (6 MONTHS - 17 YEARS)<sup>1</sup>





Itch reduction and skin clearance observed in adolescents (AD-1526), children (AD-1652), and infants to preschoolers (AD-1539) at Week 16

#### - See full clinical trial results below

**TRIAL RESULTS:** The primary endpoint in AD-1526 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 (24% of adolescents treated with DUPIXENT vs 2% with placebo, P < 0.001). In AD-1652 and AD-1539, the primary endpoint was change from baseline in the proportion of subjects with an IGA 0 or 1 at Week 16 (28% of infants to preschoolers treated with DUPIXENT + TCS vs 4% with placebo + TCS in AD-1539, P < 0.0001). Other endpoints included change from baseline in the proportion of subjects with EASI-75 at Week 16 (improvement of ≥75%; 42% of adolescents treated with DUPIXENT vs 8% with placebo in AD-1526, P < 0.001; 75% of children ≥30 kg treated with DUPIXENT + TCS vs 26% with placebo + TCS; 75% of children <30 kg treated with DUPIXENT + TCS vs 28% with placebo + TCS in AD-1652; 53% of infants to preschoolers treated with DUPIXENT + TCS vs 11% with placebo + TCS in AD-1539, P < 0.0001), itch reduction as defined by ≥4-point improvement in the Peak Pruritus NRS at Week 16 (37% of adolescents treated with DUPIXENT vs 5% with placebo in AD-1526, P < 0.001; and itch reduction defined by ≥4-point improvement in the Worst Scratch/Itch NRS at Week 16 (48% of infants to preschoolers treated with DUPIXENT + TCS vs 9% with placebo + TCS in AD-1539, P < 0.0001). 1,3,7,8

TRIAL DESIGNS: A total of 251 adolescents (12-17 years) in AD-1526 and 162 infants to preschoolers (6 months to 5 years) in AD-1539 with moderate-to-severe atopic dermatitis and 367 children (6-11 years) in AD-1652 (16 weeks each) with severe disease inadequately controlled with topical prescription therapies were randomized to DUPIXENT or placebo. All patients in AD-1652 and AD-1539 were treated with concomitant TCS. All DUPIXENT-treated 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, and children 15 kg but <30 kg received 300 mg Q4W following a 600 mg loading dose. Infants to preschoolers 15 kg but <30 kg received 300 mg Q4W, and infants to preschoolers 5 kg but <15 kg received 200 mg Q4W. In AD-1526 and AD-1539, 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%. In AD-1652, patients had an IGA score of 4, an EASI score ≥21, and BSA involvement of ≥15%. At baseline, 46% of adolescents and 23% of infants to preschoolers had an IGA score of 3 (moderate), 54% of adolescents and 77% of infants to preschoolers had an IGA of 4 (severe), mean EASI score was 36 for adolescents, 37.9 for children, and 34.1 for infants to preschoolers, and weekly averaged Peak Pruritus NRS was 8 for adolescents and 7.8 for children on a scale of 0 to 10, and weekly average of daily Worst Scratch/Itch NRS was 7.6 for infants to preschoolers on a scale of 0 to 10.1.3

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**

**ADVERSE REACTIONS:** The most common adverse reactions (incidence  $\geq 1\%$ ) 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  $\pm$  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  $\geq 2\%$ ) reported in patients 6 months to 5 years of age. These cases did not lead to study drug discontinuation.

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

#### DEMONSTRATED SAFETY PROFILE<sup>1</sup>



#### A demonstrated safety profile in patients 6+ months of age

- 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 52-week safety profile of DUPIXENT + TCS in adults was generally consistent with the Week 16 adult safety profile
- The safety profile in pediatric patients 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

#### OTHER IMPORTANT ATTRIBUTES<sup>1</sup>



NOT AN IMMUNOSUPPRESSANT OR STEROID



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



NO BOXED WARNING



NOT METABOLIZED THROUGH THE LIVER OR EXCRETED THROUGH THE KIDNEYS

• No known drug-to-drug interactions

# **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.

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



# CHANGE THEIR STORY TOGETHER BY PARTNERING WITH A SPECIALIST

Real adolescent and child patients being treated with DUPIXENT. Individual results may vary. The infant to preschooler (6 months to 5 years of age) is not an actual patient.



# CONSIDER THIS APPROACH WHEN PATIENTS WITH MODERATE-TO-SEVERE ATOPIC DERMATITIS REMAIN UNCONTROLLED DESPITE TOPICAL Rx THERAPIES







REFER TO A SPECIALIST





# FIND AN ECZEMA SPECIALIST TODAY. VISIT <u>DISCOVERDUPIXENT.COM</u>

## 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 <a href="https://mothertobaby.org/ongoing-study/dupixent/">https://mothertobaby.org/ongoing-study/dupixent/</a>. 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 <a href="here">here</a> for full Prescribing Information.

References: 1. DUPIXENT Prescribing Information. 2. Boguniewicz M, Alexis AF, Beck LA, et al. Expert perspectives on management of moderate-to-severe atopic dermatitis: a multidisciplinary consensus addressing current and emerging therapies. *J Allergy Clin Immunol Pract.* 2017;5(6):1519-1531. 3. Data on file, Regeneron Pharmaceuticals, Inc. 4. 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. 5. Leung DYM, Boguniewicz M, Howell MD, Nomura I, Hamid QA. New insights into atopic dermatitis. *J Clin Invest.* 2004;113(5):651-657. 6. 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.* 2018;120(1):10-22.e2. 7. 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. 8. 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.



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