

DOSAGE & ADMINISTRATION

DUPIXENT IS APPROVED FOR 2 DERMATOLOGIC INDICATIONS THAT ARE DRIVEN IN PART BY TYPE 2 INFLAMMATION¹



ATOPIC DERMATITIS¹

uncontrolled moderate-to-severe



PRURIGO NODULARIS¹

INDICATIONS

Atopic Dermatitis: 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.

<u>Prurigo Nodularis:</u> DUPIXENT is indicated for the treatment of adult patients with prurigo nodularis (PN).

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 and Instructions for Use.

DOSING IN UNCONTROLLED MODERATE-TO-SEVERE ATOPIC DERMATITIS

ONE DOSAGE REGIMEN IN ADULTS



18+ YFARS

One dosage regimen in adults

Initial loading dose: 600 mg 2 x 300 mg

Followed by: 300 mg Q2W 1 x 300 mg

WEIGHT-TIERED DOSAGE REGIMEN IN CHILDREN AND ADOLESCENTS^a

| Ñ. | 6 TO 17 YEARS | ≥60 kg | Initial loading dose: 600 mg 2 x 300 mg | Followed by: 300 mg Q2W 1 x 300 mg |
|--------|------------------|--------------------|--|---------------------------------------|
| | | 30 to <60 kg | Initial loading dose: 400 mg 2 x 200 mg | Followed by: 200 mg Q2W 1 x 200 mg |
| | | 15 to <30 kg | Initial loading dose: 600 mg 2 x 300 mg | Followed by: 300 mg Q4W 1 x 300 mg |
| T-TIEF | RED DOSAGE RE | GIMEN IN INFANTS T | O PRESCHOOLERS ^a | |

WEIGH1



15 to <30 kg

No initial loading dose recommended

Initial and subsequent dosage: 300 mg Q4W 1 x 300 mg

5 to <15 kg

No initial loading dose

Initial and subsequent dosage: 200 mg Q4W 1 x 200 mg

Available in a 200 mg and 300 mg pre-filled pen (for indicated patients 2+ years of age) or pre-filled syringe (for indicated patients 6+ months of age) for subcutaneous injection. Q2W, once every 2 weeks; Q4W, once every 4 weeks.

^a 5 kg is equal to 11 lb; 15 kg is equal to 33 lb; 30 kg is equal to 66 lb; 60 kg is equal to 132 lb.

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 AD subjects with conjunctivitis or keratitis recovered or were recovering during the treatment period. Conjunctivitis occurred more frequently in prurigo nodularis subjects who received DUPIXENT versus placebo; these subjects recovered or were recovering during the treatment period. There were no cases of keratitis reported in the PN development program. Conjunctivitis and keratitis have been reported with DUPIXENT in postmarketing settings, predominantly in AD 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.

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

DOSING IN PRURIGO NODULARIS

ONE DOSAGE REGIMEN IN ADULTS



18+ YEARS

Initial loading dose: **600 mg** 2 x 300 mg

Followed by: 300 mg Q2W 1 x 300 mg

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.

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:

- Atopic Dermatitis: The 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 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.
- Prurigo Nodularis: The most common adverse reactions (incidence ≥2%) are nasopharyngitis, conjunctivitis, herpes infection, dizziness, myalgia, and diarrhea.

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.





DUPIXENT OFFERS MULTIPLE ADMINISTRATION OPTIONS FOR YOU AND YOUR PATIENTS

AVAILABLE IN A 200 mg AND 300 mg PRE-FILLED PEN (FOR INDICATED PATIENTS 2+ YEARS OF AGE) OR PRE-FILLED SYRINGE (FOR INDICATED PATIENTS 6+ MONTHS OF AGE) FOR SUBCUTANEOUS INJECTION¹

For indicated ages 2+ years



For indicated ages 6+ months



200 mg and 300 mg injectable shown.

- DUPIXENT is administered by subcutaneous injection and is intended for use under the guidance of a healthcare provider¹
- Rotate the injection site with each injection¹
- Provide proper training to patients and/or caregivers on the preparation and administration of DUPIXENT prior to use, according to the Instructions for Use¹
- Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with DUPIXENT¹

A caregiver or patient 12 years of age and older may inject DUPIXENT using the pre-filled syringe or pre-filled pen. In pediatric patients 12 to 17 years of age, administer DUPIXENT under the supervision of an adult. In pediatric patients 6 months to less than 12 years of age, administer DUPIXENT by a caregiver.¹



AT-HOME ADMINISTRATION



IN-OFFICE ADMINISTRATION



PRE-FILLED PEN (2+ YEARS) OR SYRINGE (6+ MONTHS)

- In AD and PN, if an every-other-week dose is missed, instruct the patient to
 administer the injection within 7 days from the missed dose and then resume their
 original schedule. If the missed dose is not administered within 7 days, instruct the
 patient to wait until the next dose on the original schedule¹
- In AD, if an every-4-week dose is missed, instruct the patient to administer the
 injection within 7 days from the missed dose and then resume their original
 schedule. If the missed dose is not administered within 7 days, instruct the patient to
 administer the dose, starting a new schedule based on this date¹

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Visit **DUPIXENT.COM** to view administration videos

Reference: 1. DUPIXENT Prescribing Information.



