DOSAGE & ADMINISTRATION

DUPIXENT® *(dupilumab) Injection*
200mg · 300mg

APPROVED IN 9 INDICATIONS DRIVEN IN PART BY TYPE 2 INFLAMMATION[1]

DERMATOLOGY



ATOPIC DERMATITIS
DUPIXENT is indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis (AD) 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.



PRURIGO NODULARIS
DUPIXENT is indicated for the treatment of adult patients with prurigo nodularis (PN).



CHRONIC SPONTANEOUS URTICARIA
DUPIXENT is indicated for the treatment of adult and pediatric patients aged 2 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.
Limitations of Use: DUPIXENT is not indicated for treatment of other forms of urticaria.



BULLOUS PEMPHIGOID
DUPIXENT is indicated for the treatment of adult patients with bullous pemphigoid (BP).

RESPIRATORY



ASTHMA
DUPIXENT is indicated as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
Limitations of Use: DUPIXENT is not indicated for the relief of acute bronchospasm or status asthmaticus.



CHRONIC OBSTRUCTIVE PULMONARY DISEASE
DUPIXENT is indicated as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
Limitations of Use: DUPIXENT is not indicated for the relief of acute bronchospasm.



CHRONIC RHINOSINUSITIS WITH NASAL POLYPS
DUPIXENT is indicated as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).



ALLERGIC FUNGAL RHINOSINUSITIS
DUPIXENT is indicated for the treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery.

GASTROENTEROLOGY



EOSINOPHILIC ESOPHAGITIS
DUPIXENT is indicated for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).

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.

UNCONTROLLED MODERATE-TO-SEVERE ATOPIC DERMATITIS (AD)

ADULTS (18+ YEARS) ONE DOSAGE REGIMEN[1]

18+ YEARS	One dosage regimen in adults	Initial loading dose: **600 mg** 2 x 300 mg	Followed by: **300 mg Q2W** 1 x 300 mg

CHILDREN AND ADOLESCENTS (6 YEARS TO 17 YEARS) WEIGHT-TIERED DOSAGE REGIMEN[1,a]

6 YEARS 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

INFANTS TO PRESCHOOLERS (6 MONTHS TO 5 YEARS) WEIGHT-TIERED DOSAGE REGIMEN[1,a]

6 MONTHS TO 5 YEARS	15 to <30 kg	No initial loading dose recommended	**300 mg Q4W** 1 x 300 mg
	5 to <15 kg	No initial loading dose recommended	**200 mg Q4W** 1 x 200 mg

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.

HOW DUPIXENT IS SUPPLIED

Choice of administration: Available in a 200 mg and 300 mg single-dose pre-filled pen (for indicated patients 2+ years of age) or pre-filled syringe (for indicated patients 6+ months of age) for subcutaneous injection[1]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions, including anaphylaxis, acute generalized exanthematous pustulosis (AGEP), serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported.

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

DUPIXENT® (dupilumab) Injection
200mg · 300mg

PRURIGO NODULARIS (PN)

ADULTS (18+ YEARS) ONE DOSAGE REGIMEN[1]



18+ YEARS | **One dosage regimen in adults** | **Initial loading dose:** **600 mg** 2 x 300 mg | **Followed by:** **300 mg Q2W** 1 x 300 mg

Q2W, once every 2 weeks.

HOW DUPIXENT IS SUPPLIED



Choice of administration: Available in a 300 mg single-dose pre-filled pen (for indicated patients 18+ years of age) or pre-filled syringe (for indicated patients 18+ years of age) for subcutaneous injection[1]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity (cont'd): A case of AGEP was reported in an adult subject who participated in the bullous pemphigoid development program. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

Conjunctivitis, Keratitis, and Blepharitis: Conjunctivitis and keratitis occurred more frequently in AD, COPD, and BP subjects who received DUPIXENT versus placebo, with conjunctivitis being the most frequently reported eye disorder in AD. Conjunctivitis also occurred more frequently in adult CRSwNP and PN subjects who received DUPIXENT compared to those who received placebo. Conjunctivitis, keratitis, and blepharitis have been reported with DUPIXENT in postmarketing settings, predominantly in AD patients. Some patients reported varying degrees of transient or ongoing visual impairment including blindness associated with conjunctivitis, keratitis, or blepharitis leading to discontinuation of DUPIXENT and/or surgical intervention. Advise patients or their caregivers to promptly report new-onset or worsening eye symptoms to their healthcare provider. Consider discontinuation of DUPIXENT and prompt ophthalmological examination for patients who develop signs and symptoms suggestive of keratitis, or when conjunctivitis or blepharitis do not resolve following standard treatment, as appropriate. Use with caution in patients with significant dry eye disease, history of significant lid abnormalities/surgeries, or history of nasolacrimal surgery.

Eosinophilic Conditions: Patients being treated for asthma may present with clinical features of eosinophilic pneumonia or eosinophilic granulomatosis with polyangiitis (EGPA). These events may be associated with the reduction of oral corticosteroid therapy. Healthcare providers should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, kidney injury, and/or neuropathy presenting in their patients with eosinophilia.

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

DUPIXENT® (dupilumab) Injection 300mg

CHRONIC SPONTANEOUS URTICARIA (CSU) SYMPTOMATIC DESPITE H1 ANTIHISTAMINES

ADULTS (18+ YEARS) ONE DOSAGE REGIMEN[1]

		Initial loading dose:	Followed by:
18+ YEARS	One dosage regimen in adults	**600 mg** 2 x 300 mg	**300 mg Q2W** 1 x 300 mg

CHILDREN AND ADOLESCENTS (6 YEARS TO 17 YEARS) WEIGHT-TIERED DOSAGE REGIMEN[1,a]

		Initial loading dose:	Followed by:
6 YEARS TO 17 YEARS	15 to <30 kg	**600 mg** 2 x 300 mg injections	**300 mg Q4W**
	30 to <60 kg	**400 mg** 2 x 200 mg injections	**200 mg Q2W**
	60 kg or more	**600 mg** 2 x 300 mg injections	**300 mg Q2W**

PEDIATRIC PATIENTS (2 YEARS TO 5 YEARS)

2 YEARS TO 5 YEARS	5 to <15 kg	No initial loading dose recommended	**200 mg Q4W** 1 x 200 mg
	15 to <30 kg	No initial loading dose recommended	**300 mg Q4W** 1 x 300 mg

Q2W, once every 2 weeks; Q4W, once every 4 weeks.
[a] 30 kg is equal to 66 lb; 60 kg is equal to 132 lb.

HOW DUPIXENT IS SUPPLIED

Choice of administration: Available in a 200 mg and 300 mg single-dose pre-filled pen (for indicated patients 2+ years of age) or pre-filled syringe (for indicated patients 2+ years of age) for subcutaneous injection[1]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Eosinophilic Conditions (cont'd): Cases of eosinophilic pneumonia were reported in adults who participated in the asthma development program and cases of EGPA have been reported with DUPIXENT in adults who participated in the asthma development program as well as in adults with co-morbid asthma in the CRSwNP development program. Advise patients to report signs of eosinophilic pneumonia and EGPA. Consider withholding DUPIXENT if eosinophilic pneumonia or EGPA are suspected.

Acute Symptoms of Asthma or Chronic Obstructive Pulmonary Disease or Acute Deteriorating Disease: Do not use DUPIXENT to treat acute symptoms or acute exacerbations of asthma or COPD, acute bronchospasm, or status asthmaticus. Patients should seek medical advice if their asthma or COPD remains uncontrolled or worsens after initiation of DUPIXENT.

Risk Associated with Abrupt Reduction of Corticosteroid Dosage: Do not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of DUPIXENT.

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

DUPIXENT® (dupilumab) Injection
200mg · 300mg

BULLOUS PEMPHIGOID (BP)

ADULTS (18+ YEARS) ONE DOSAGE REGIMEN[1]

18+ YEARS	One dosage regimen in adults regardless of weight	Initial loading dose: **600 mg** 2 x 300 mg	Followed by: **300 mg Q2W** 1 x 300 mg Use DUPIXENT in combination with a tapering course of oral corticosteroids.

Use DUPIXENT in combination with a tapering course of oral corticosteroids. Once disease control has occurred, gradually taper corticosteroids after which continue DUPIXENT as monotherapy. In case of relapse, corticosteroids may be added if medically advisable.

Q2W, once every 2 weeks

HOW DUPIXENT IS SUPPLIED

Choice of administration: Available in a 300 mg single-dose pre-filled pen (for indicated patients 18+ years of age) or pre-filled syringe (for indicated patients 18+ years of age) for subcutaneous injection[1]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Risk Associated with Abrupt Reduction of Corticosteroid Dosage (cont'd): 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 with co-morbid asthma not to adjust or stop their asthma treatments without consultation with their physicians.

Psoriasis: Cases of new-onset psoriasis have been reported with the use of DUPIXENT for the treatment of atopic dermatitis and asthma, including in patients without a family history of psoriasis. In postmarketing reports, these cases resulted in partial or complete resolution of psoriasis with discontinuation of dupilumab, with or without use of supplemental treatment for psoriasis (topical or systemic). Those who continued dupilumab received supplemental treatment for psoriasis to improve associated symptoms. Advise patients to report new-onset psoriasis symptoms. If symptoms persist or worsen, consider dermatologic evaluation and/or discontinuation of DUPIXENT.

Arthralgia and Psoriatic Arthritis: 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. Cases of new-onset psoriatic arthritis requiring systemic treatment have been reported with the use of DUPIXENT. 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.

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

DUPIXENT® (dupilumab) Injection 300mg

MODERATE-TO-SEVERE ASTHMA

ADULTS AND ADOLESCENT PATIENTS (12+ YEARS) TWO DOSAGE REGIMENS[1]

For patients with moderate-to-severe asthma characterized by an eosinophilic phenotype of ≥150 cells/µL[1]



12+ YEARS

Initial loading dose:		Followed by:
600 mg 2 x 300 mg	OR	**300 mg Q2W** 1 x 300 mg
400 mg 2 x 200 mg		**200 mg Q2W** 1 x 200 mg

For patients with OCS-dependent asthma or comorbid moderate-to-severe atopic dermatitis, CRSwNP, or AFRS:

- Initial loading dose is 600 mg (2 x 300 mg) followed by Q2W dosing of 1 x 300 mg

For pediatric patients 12 years to 17 years of age (>60 kg) and adults with AFRS

CHILDREN (6 YEARS TO 11 YEARS) WEIGHT-TIERED DOSAGE REGIMEN[1,a]



6 YEARS TO 11 YEARS

30 kg or more	**No initial loading dose recommended**	**200 mg Q2W** 1 x 200 mg
15 kg to <30 kg	**No initial loading dose recommended**	**300 mg Q4W** 1 x 300 mg

For pediatric patients (6 years to 11 years of age) with asthma and comorbid moderate-to-severe atopic dermatitis, follow the recommended dosage for pediatric patients with moderate-to-severe atopic dermatitis, which includes an initial loading dose.

CRSwNP, chronic rhinosinusitis with nasal polyps; OCS, oral corticosteroid; Q2W, once every 2 weeks; Q4W, once every 4 weeks.

[a] 15 kg is equal to 33 lb; 30 kg is equal to 66 lb.

HOW DUPIXENT IS SUPPLIED



Choice of administration: Available in a 200 mg and 300 mg single-dose pre-filled pen (for indicated patients 6+ years of age) or pre-filled syringe (for indicated patients 6+ years of age) for subcutaneous injection[1]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Parasitic (Helminth) Infections (cont'd):

Helminth infections (5 cases of enterobiasis and 1 case of ascariasis) were reported in pediatric patients 6 to 11 years old in the pediatric asthma development program.

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 here for full Prescribing Information.

DUPIXENT® (dupilumab) Injection
200mg · 300mg

INADEQUATELY CONTROLLED CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

ADULTS (18+ YEARS) ONE DOSAGE REGIMEN[1]

For patients with inadequately controlled COPD and an eosinophilic phenotype (EOS ≥300 cells/µL)[1]

18+ YEARS | **One dosage regimen in adults** | **No initial loading dose recommended** | **300 mg Q2W** 1 x 300 mg

Q2W, once every 2 weeks.

HOW DUPIXENT IS SUPPLIED

Choice of administration: Available in a 300 mg single-dose pre-filled pen (for indicated patients 18+ years of age) or pre-filled syringe (for indicated patients 18+ years of age) for subcutaneous injection[1]

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS:

Most common adverse reactions are:

- **Atopic Dermatitis** (incidence ≥1%): 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 AD. 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 AD, 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.
- **Asthma** (incidence ≥1%): injection site reactions, oropharyngeal pain, and eosinophilia.
- **Chronic Rhinosinusitis with Nasal Polyps** (incidence ≥1% in adult patients): injection site reactions, eosinophilia, insomnia, toothache, gastritis, arthralgia, and conjunctivitis.
- **Eosinophilic Esophagitis** (incidence ≥2%): injection site reactions, upper respiratory tract infections, arthralgia, and herpes viral infections.
- **Prurigo Nodularis** (incidence ≥2%): nasopharyngitis, conjunctivitis, herpes infection, dizziness, myalgia, and diarrhea.
- **Chronic Spontaneous Urticaria** (incidence ≥2% in patients 12 years of age and older): injection site reactions.
- **Bullous Pemphigoid** (incidence ≥2%): arthralgia, conjunctivitis, vision blurred, herpes viral infections, keratitis.
- **Allergic Fungal Rhinosinusitis** The most common adverse reactions in patients with AFRS are similar to adverse reactions for CRSwNP.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** A pregnancy exposure registry monitors pregnancy outcomes in women exposed to DUPIXENT during pregnancy. 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.

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

DUPIXENT® (dupilumab) Injection 300mg

INADEQUATELY CONTROLLED CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP)

ADULTS AND ADOLESCENT PATIENTS (12+ YEARS) ONE DOSAGE REGIMEN[1]



12+ YEARS | **One dosage regimen in adults and adolescents** | **No initial loading dose recommended** | **300 mg Q2W** 1 x 300 mg

Q2W, once every 2 weeks.

HOW DUPIXENT IS SUPPLIED



Choice of administration: Available in a 300 mg single-dose pre-filled pen (for indicated patients 12+ years of age) or pre-filled syringe (for indicated patients 12+ years of age) for subcutaneous injection[1]

IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS (cont'd)

- **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.

CONTRAINDICATION: DUPIXENT is contraindicated in patients with known hypersensitivity to dupilumab or any of its excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions, including anaphylaxis, acute generalized exanthematous pustulosis (AGEP), serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported. A case of AGEP was reported in an adult subject who participated in the bullous pemphigoid development program. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

Conjunctivitis, Keratitis, and Blepharitis: Conjunctivitis and keratitis occurred more frequently in AD, COPD, and BP subjects who received DUPIXENT versus placebo, with conjunctivitis being the most frequently reported eye disorder in AD. Conjunctivitis also occurred more frequently in adult CRSwNP and PN subjects who received DUPIXENT compared to those who received placebo. Conjunctivitis, keratitis, and blepharitis have been reported with DUPIXENT in postmarketing settings, predominantly in AD patients. Some patients reported varying degrees of transient or ongoing visual impairment including blindness associated with conjunctivitis, keratitis, or blepharitis leading to discontinuation of DUPIXENT and/or surgical intervention. Advise patients or their caregivers to promptly report new-onset or worsening eye symptoms to their healthcare provider. Consider discontinuation of DUPIXENT and prompt ophthalmological examination for patients who develop signs and symptoms suggestive of keratitis, or when conjunctivitis or blepharitis do not resolve following standard treatment, as appropriate. Use with caution in patients with significant dry eye disease, history of significant lid abnormalities/surgeries, or history of nasolacrimal surgery.

Eosinophilic Conditions: Patients being treated for asthma may present with clinical features of eosinophilic pneumonia or eosinophilic granulomatosis with polyangiitis (EGPA). These events may be associated with the reduction of oral corticosteroid therapy. Healthcare providers should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, kidney injury, and/or neuropathy presenting in their patients with eosinophilia.

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

DUPIXENT® (dupilumab) Injection 300mg

ALLERGIC FUNGAL RHINOSINUSITIS

ADULTS (18+ YEARS) ONE DOSAGE REGIMEN

18+ YEARS	One dosage regimen in adults	No initial loading dose recommended	**300 mg Q2W** 1 x 300 mg

PEDIATRIC AND ADOLESCENT PATIENTS (6 YEARS TO 17 YEARS) WEIGHT-TIERED DOSING REGIMEN

6 YEARS TO 17 YEARS	15 to <30 kg	No initial loading dose recommended	**300 mg Q4W** 1 x 300 mg
	30 to <60 kg	No initial loading dose recommended	**200 mg Q2W** 1 x 200 mg
	≥60 kg	No initial loading dose recommended	**300 mg Q2W** 1 x 300 mg

Q2W, once every 2 weeks; Q4W, once every 4 weeks.

HOW DUPIXENT IS SUPPLIED

Choice of administration: Available in a 200 mg and 300 mg single-dose pre-filled pen (for indicated Patients 6+ years of age) or pre-filled syringe (for indicated patients 6+ years of age) for subcutaneous injection[1]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Eosinophilic Conditions (cont'd): Cases of eosinophilic pneumonia were reported in adults who participated in the asthma development program and cases of EGPA have been reported with DUPIXENT in adults who participated in the asthma development program as well as in adults with co-morbid asthma in the CRSwNP development program. Advise patients to report signs of eosinophilic pneumonia and EGPA. Consider withholding DUPIXENT if eosinophilic pneumonia or EGPA are suspected.

Acute Symptoms of Asthma or Chronic Obstructive Pulmonary Disease or Acute Deteriorating Disease: Do not use DUPIXENT to treat acute symptoms or acute exacerbations of asthma or COPD, acute bronchospasm, or status asthmaticus. Patients should seek medical advice if their asthma or COPD remains uncontrolled or worsens after initiation of DUPIXENT.

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 with co-morbid asthma not to adjust or stop their asthma treatments without consultation with their physicians.

Psoriasis: Cases of new-onset psoriasis have been reported with the use of DUPIXENT for the treatment of atopic dermatitis and asthma, including in patients without a family history of psoriasis. In postmarketing reports, these cases resulted in partial or complete resolution of psoriasis with discontinuation of dupilumab, with or without use of supplemental treatment for psoriasis (topical or systemic). Those who continued dupilumab received supplemental treatment for psoriasis to improve associated symptoms. Advise patients to report new-onset psoriasis symptoms. If symptoms persist or worsen, consider dermatologic evaluation and/or discontinuation of DUPIXENT.

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DUPIXENT® (dupilumab) Injection 300mg

EOSINOPHILIC ESOPHAGITIS (EoE)

ADULT AND PEDIATRIC PATIENTS (1+ YEAR) WEIGHT-TIERED DOSAGE REGIMEN[1,a]

1+ YEAR	≥40 kg	No initial loading dose recommended	**300 mg QW** 1 x 300 mg
	30 to <40 kg	No initial loading dose recommended	**300 mg Q2W** 1 x 300 mg
	15 to <30 kg	No initial loading dose recommended	**200 mg Q2W** 1 x 200 mg

QW, once weekly; Q2W, once every 2 weeks.

[a] 15 kg is equal to 33 lb; 30 kg is equal to 66 lb; 40 kg is equal to 88 lb.

HOW DUPIXENT IS SUPPLIED

Choice of administration: Available in a 200 mg and 300 mg single-dose pre-filled pen (for indicated patients 2+ years of age) or pre-filled syringe (for indicated patients 1+ years of age) for subcutaneous injection[1]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Arthralgia and Psoriatic Arthritis: 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. Cases of new-onset psoriatic arthritis requiring systemic treatment have been reported with the use of DUPIXENT. 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.

ADVERSE REACTIONS:

Most common adverse reactions are:

- **Atopic Dermatitis** (incidence ≥1%): 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 AD. 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 AD, 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.
- **Asthma** (incidence ≥1%): injection site reactions, oropharyngeal pain, and eosinophilia.
- **Chronic Rhinosinusitis with Nasal Polyps** (incidence ≥1% in adult patients): injection site reactions, eosinophilia, insomnia, toothache, gastritis, arthralgia, and conjunctivitis.
- **Eosinophilic Esophagitis** (incidence ≥2%): injection site reactions, upper respiratory tract infections, arthralgia, and herpes viral infections.
- **Prurigo Nodularis** (incidence ≥2%): nasopharyngitis, conjunctivitis, herpes infection, dizziness, myalgia, and diarrhea.
- **Chronic Obstructive Pulmonary Disease** (incidence ≥2%): viral infection, headache, nasopharyngitis, back pain, diarrhea, arthralgia, urinary tract infection, local administration reactions, rhinitis, eosinophilia, toothache, and gastritis.
- **Chronic Spontaneous Urticaria** (incidence ≥2%): injection site reactions.
- **Bullous Pemphigoid** (incidence ≥2%): arthralgia, conjunctivitis, vision blurred, herpes viral infections, keratitis.

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DUPIXENT® (dupilumab) Injection
200mg · 300mg

MULTIPLE ADMINISTRATION OPTIONS

PRE-FILLED PEN (FOR AGES 2+ YEARS)[1,2]

- Subcutaneous autoinjector with hidden needle
- Needle cap is not made with natural rubber latex
- Visual and audible feedback
- Available in 200 mg and 300 mg



PRE-FILLED SYRINGE (FOR AGES 6+ MONTHS)[1,3]

- Subcutaneous injection with needle shield
- Includes finger grip
- Needle cap is not made with natural rubber latex
- Available in 200 mg and 300 mg



AVAILABILITY

- DUPIXENT is available in cartons containing 2 single-dose pre-filled pens or 2 single-dose pre-filled syringes
  - The pre-filled pen is designed to deliver **300 mg** of DUPIXENT in a **2 mL** (150 mg/mL) solution or **200 mg** in a **1.14 mL** (175 mg/mL) solution
  - The pre-filled syringe is designed to deliver **300 mg** of DUPIXENT in a **2 mL** (150 mg/mL) solution or **200 mg** in a **1.14 mL** (175 mg/mL) solution



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.

CONTRAINDICATION: DUPIXENT is contraindicated in patients with known hypersensitivity to dupilumab or any of its excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity: Hypersensitivity reactions, including anaphylaxis, acute generalized exanthematous pustulosis (AGEP), serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum, and erythema multiforme have been reported. A case of AGEP was reported in an adult subject who participated in the bullous pemphigoid development program. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT.

Conjunctivitis, Keratitis, and Blepharitis: Conjunctivitis and keratitis occurred more frequently in AD, COPD, and BP subjects who received DUPIXENT versus placebo, with conjunctivitis being the most frequently reported eye disorder in AD. Conjunctivitis also occurred more frequently in adult CRSwNP and PN subjects who received DUPIXENT compared to those who received placebo. Conjunctivitis, keratitis, and blepharitis have been reported with DUPIXENT in postmarketing settings, predominantly in AD patients. Some patients reported varying degrees of transient or ongoing visual impairment including blindness associated with conjunctivitis, keratitis, or blepharitis leading to discontinuation of DUPIXENT and/or surgical intervention.

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DUPIXENT® (dupilumab) Injection
200mg · 300mg

ADMINISTERING DUPIXENT

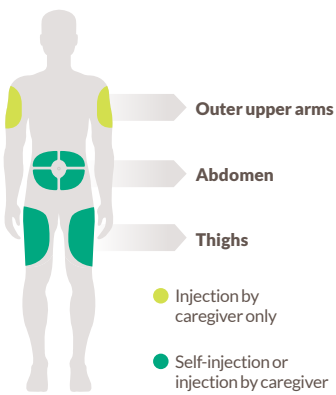
HOW TO TAKE DUPIXENT[1]

- DUPIXENT is intended for use under the guidance of a healthcare provider
- A patient may self-inject DUPIXENT after receiving training in subcutaneous injection technique
  - In children 6 months to less than 12 years of age, DUPIXENT should be given by a caregiver
  - In children 12 years of age and older, it is recommended that DUPIXENT be given by or under the supervision of an adult
- DUPIXENT can be administered in the office under the guidance of a healthcare provider if the patient is not an appropriate candidate for at-home administration
- Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with DUPIXENT

ADMINISTER AT DIFFERENT INJECTION SITES[1-3]

Remember to provide proper training to patients and/or caregivers on the preparation and administration of DUPIXENT prior to use, according to the Instructions for Use

- When administering a loading dose (consisting of 2 injections), remember to administer each injection into a different site
- Administer the subcutaneous injection into the thigh or abdomen, except for the 2 inches (5 cm) around the navel
- The upper arm can also be used if a caregiver administers the injection
- Rotate the injection site with each injection. **DO NOT** inject DUPIXENT into skin that is tender, damaged, bruised, or scarred



MISSED DOSE INFORMATION[1]

- If a weekly dose is missed, administer the dose as soon as possible, and start a new weekly schedule from the date of the last administered dose
- If an every-2-week dose is missed, instruct the patient to administer the injection within 7 days from the missed dose and then resume the original schedule. If the missed dose is not administered within 7 days, administer the dose starting a new schedule based on this date
- 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 the 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 date

DUPIXENT prescriptions can only be filled by specialty pharmacies that provide appropriate handling and shipping to home. ***DUPIXENT MyWay®*** offers further patient access and support.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Conjunctivitis, Keratitis, and Blepharitis (cont'd): Advise patients or their caregivers to promptly report new-onset or worsening eye symptoms to their healthcare provider. Consider discontinuation of DUPIXENT and prompt ophthalmological examination for patients who develop signs and symptoms suggestive of keratitis, or when conjunctivitis or blepharitis do not resolve following standard treatment, as appropriate. Use with caution in patients with significant dry eye disease, history of significant lid abnormalities/surgeries, or history of nasolacrimal surgery.

Eosinophilic Conditions: Patients being treated for asthma may present with clinical features of eosinophilic pneumonia or eosinophilic granulomatosis with polyangiitis (EGPA). These events may be associated with the reduction of oral corticosteroid therapy. Healthcare providers should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, kidney injury, and/or neuropathy presenting in their patients with eosinophilia.

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

DUPIXENT® (dupilumab) Injection
200mg · 300mg

GETTING YOUR PATIENTS STARTED WITH DUPIXENT

DUPIXENT MyWay® CAN HELP ELIGIBLE PATIENTS START AND STAY ON TRACK WITH DUPIXENT

- HELP TO UNDERSTAND AND NAVIGATE THE INSURANCE PROCESS FOR DUPIXENT
- **THE QUICK START PROGRAM** may be able to temporarily provide DUPIXENT at no cost to help bridge patients to therapy if there is a coverage delay. Subject to the eligibility requirements listed below[a]
- COPAY AND FINANCIAL ASSISTANCE FOR ELIGIBLE PATIENTS[b]
- SUPPLEMENTAL INJECTION TRAINING IN PERSON, VIRTUALLY, OR BY PHONE
- TEXT AND EMAIL REMINDERS FOR PATIENTS TO TAKE THEIR NEXT DOSE AND REFILL THEIR PRESCRIPTION
- TIPS AND TOOLS TO HELP PATIENTS MANAGE THEIR TREATMENT PLANS

DUPIXENT MyWay support begins with the enrollment form. Speak with your field representative, visit **DupixentHCP.com**, or call **1-844-DUPIXENT** to get started

[a] [Patients may be eligible for the Quick Start Program if they: have a valid DUPIXENT prescription for an FDA-approved indication, are new to DUPIXENT, have prescription drug coverage for DUPIXENT through a commercial insurance plan not funded through a government healthcare program, are a resident of the United States, District of Columbia, or Puerto Rico and are treated by a licensed prescriber therein, are not an inpatient, are experiencing a coverage delay, and are actively seeking coverage through their insurance provider. Some patients may be subject to additional diagnostic criteria for eligibility.]

[b] [Subject to the program maximum per patient per calendar year. Approval is not guaranteed. **THIS IS NOT INSURANCE**. Not valid for prescriptions paid, in whole or in part, by Medicaid, Medicare, VA, DOD, TRICARE, or other federal or state programs, including any state pharmaceutical assistance programs. This program is not valid where prohibited by law, taxed, or restricted. *DUPIXENT MyWay* reserves the right to rescind, revoke, terminate, or amend this offer, eligibility, and terms of use at any time without notice. Any savings provided by the program may vary depending on patients' out-of-pocket costs. The program is intended to help patients afford DUPIXENT. Patients may have insurance plans that attempt to dilute the impact of the assistance available under the program. In those situations, the program may change its terms. Additional terms and conditions apply.]

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

DUPIXENT® (dupilumab) Injection
200mg · 300mg

ADMINISTRATION OPTIONS AND OTHER CONSIDERATIONS FOR YOU AND YOUR PATIENT

AT-HOME SELF-ADMINISTRATION

- Train patients and/or caregivers on proper preparation and administration prior to use

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

PRE-FILLED SYRINGE
(for indicated patients 6+ months of age)

PRE-FILLED PEN
(for indicated patients 2+ years of age)

SCAN HERE TO VIEW SUPPLEMENTAL INSTRUCTIONAL ADMINISTRATION VIDEOS

Patients and caregivers can visit ***DUPIXENT.COM*** or call **1-844-DUPIXENT** to learn more about support available through ***DUPIXENT MyWay***

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Eosinophilic Conditions (cont'd): Cases of eosinophilic pneumonia were reported in adults who participated in the asthma development program and cases of EGPA have been reported with DUPIXENT in adults who participated in the asthma development program as well as in adults with co-morbid asthma in the CRSwNP development program. Advise patients to report signs of eosinophilic pneumonia and EGPA. Consider withholding DUPIXENT if eosinophilic pneumonia or EGPA are suspected.

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

References: 1. DUPIXENT Prescribing Information. **2.** DUPIXENT 200 mg/300 mg Pre-filled Pen Instructions for Use. **3.** DUPIXENT 200 mg/300 mg Pre-filled Syringe Instructions for Use.

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DUPIXENT® (dupilumab) Injection
200mg · 300mg

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