DUPIXENT® (dupilumab) Injection
200mg · 300mg

DOSING & ADMINISTRATION

DUPIXENT DOSING IN 3 DISEASES WHERE TYPE 2 INFLAMMATION IS ONE OF THE KEY DRIVERS OF PATHOBIOLOGY

ATOPIC DERMATITIS
Patients 6+ years

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.

ASTHMA
Patients 12+ years

DUPIXENT is indicated as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. Limitation of Use: DUPIXENT is not indicated for the relief of acute bronchospasm or status asthmaticus.

CRSwNP
Patients 18+ years

DUPIXENT is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

Inflammation is an important component in the pathogenesis of atopic dermatitis, asthma, and CRSwNP[1]

The mechanism of dupilumab action in asthma has not been definitively established.

300 mg Pre-filled Pen Now Available for Patients 12+ Years

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.

DOSING FOR UNCONTROLLED MODERATE-TO-SEVERE ATOPIC DERMATITIS

ADULTS (18+ years)[1]

Sample prescription for a 300 mg dose Q2W

DUPIXENT® (dupilumab)
300 mg/2 mL PRE-FILLED PEN OR SYRINGE 2-PACK

INITIAL DOSE: # OF 2-PACKS
600 mg QTY: 1

Sig: 2 injections subcutaneously on **Day 1**[a]
(BOTH PRE-FILLED PENS OR SYRINGES OF THE 2-PACK)

MAINTENANCE DOSE: # OF 2-PACKS REFILLS
300 mg QTY: 1 _____

Sig: 1 injection **2 weeks** after on **Day 15**
(1ST PRE-FILLED PEN OR SYRINGE OF THE 2-PACK)

and **1** injection **2 weeks** after on **Day 29**
(2ND PRE-FILLED PEN OR SYRINGE OF THE 2-PACK)
and every **2 weeks** thereafter

1 refill provides 4 weeks of maintenance therapy.

[a] Different injection sites need to be used.
Q2W, once every 2 weeks.

CHOICE OF ADMINISTRATION: AVAILABLE IN A 300 mg PRE-FILLED PEN (12+ YEARS) OR SYRINGE

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.

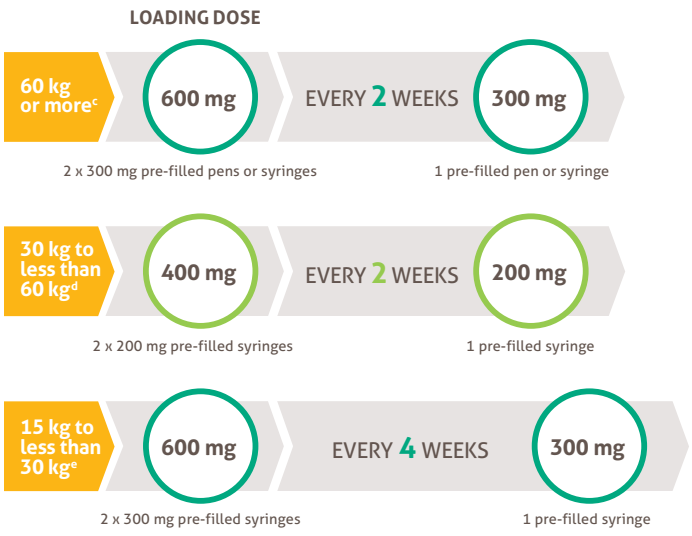
Conjunctivitis and Keratitis: Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received DUPIXENT with conjunctivitis being the most frequently reported eye disorder in these patients. Conjunctivitis also occurred more frequently in chronic rhinosinusitis with nasal polyposis subjects who received DUPIXENT. Advise patients to report new onset or worsening eye symptoms to their healthcare provider.

Eosinophilic Conditions: Patients being treated for asthma may present with serious systemic eosinophilia sometimes presenting with clinical features of eosinophilic pneumonia or vasculitis consistent with eosinophilic granulomatosis with polyangiitis (EGPA), conditions which are often treated with systemic corticosteroid therapy.

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

PEDIATRIC PATIENTS (6-17 years)[1,b]

Weight-tiered dosage regimen



[b] The DUPIXENT 300 mg Pre-filled Pen is approved for patients aged 12+ years.
[c] 60 kg is equal to 132 lb.
[d] 30 kg is equal to 66 lb.
[e] 15 kg is equal to 33 lb.

Sample prescription for a 300 mg dose Q4W

DUPIXENT® (dupilumab)
300 mg/2 mL PRE-FILLED SYRINGE 2-PACK

INITIAL DOSE: # OF 2-PACKS
600 mg QTY: 1

Sig: 2 injections subcutaneously on **Day 1**
(BOTH PRE-FILLED SYRINGES OF THE 2-PACK)

MAINTENANCE DOSE: # OF 2-PACKS REFILLS
300 mg QTY: 1 _____

Sig: 1 injection **4 weeks** after on **Day 29**
(1ST PRE-FILLED SYRINGE OF THE 2-PACK)

and **1** injection **4 weeks** after on **Day 58**
(2ND PRE-FILLED SYRINGE OF THE 2-PACK)
and every **4 weeks** thereafter

1 refill provides 8 weeks of maintenance therapy.

Q4W, once every 4 weeks.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

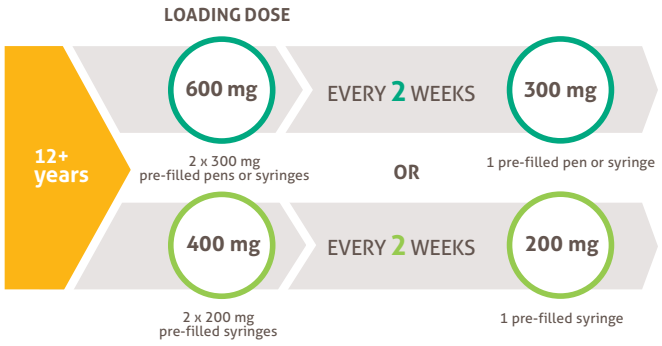
Eosinophilic Conditions (cont'd): These events may be associated with the reduction of oral corticosteroid therapy. Physicians should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients with eosinophilia.

DUPIXENT® (dupilumab)

DOSING FOR MODERATE-TO-SEVERE ASTHMA

ADULTS/ADOLESCENTS (12+ years)[1]

Moderate-to-severe asthma with an eosinophilic phenotype



OCS-dependent asthma or patients with comorbid moderate-to-severe atopic dermatitis for which DUPIXENT is indicated

- Initial dose is 600 mg (two 300 mg pre-filled pens or syringes) followed by every-2-week dosing of a 300 mg pre-filled pen or syringe

Sample prescription for a 300 mg dose Q2W

DUPIXENT® (dupilumab)
300 mg/2 mL PRE-FILLED PEN OR SYRINGE 2-PACK

INITIAL DOSE: # OF 2-PACKS
600 mg QTY: 1

Sig: 2 injections subcutaneously on **Day 1**[a]
(BOTH PRE-FILLED PENS OR SYRINGES OF THE 2-PACK)

MAINTENANCE DOSE: # OF 2-PACKS REFILLS
300 mg QTY: 1

Sig: 1 injection **2 weeks** after on **Day 15**
(1ST PRE-FILLED PEN OR SYRINGE OF THE 2-PACK)

and **1** injection **2 weeks** after on **Day 29**
(2ND PRE-FILLED PEN OR SYRINGE OF THE 2-PACK)
and every **2 weeks** thereafter

1 refill provides 4 weeks of maintenance therapy.

OCS, oral corticosteroid.

CHOICE OF ADMINISTRATION: AVAILABLE IN A 300 mg PRE-FILLED PEN (12+ YEARS) OR SYRINGE

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

Eosinophilic Conditions (cont'd): Cases of eosinophilic pneumonia were reported in adult patients who participated in the asthma development program and cases of vasculitis consistent with EGPA have been reported with DUPIXENT in adult patients who participated in the asthma development program as well as in adult patients with co-morbid asthma in the CRSwNP development program. A causal association between DUPIXENT and these conditions has not been established.

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

DOSING FOR INADEQUATELY CONTROLLED CRSwNP

ADULTS (18+ years)[1]

Inadequately controlled CRSwNP

Sample prescription for a 300 mg dose Q2W (no loading dose)

DUPIXENT® (dupilumab)
300 mg/2 mL PRE-FILLED PEN OR SYRINGE 2-PACK

MAINTENANCE DOSE: # OF 2-PACKS REFILLS
300 mg QTY: 1

Sig: 1 injection subcutaneously on **Day 1**
(1ST PRE-FILLED PEN OR SYRINGE OF THE 2-PACK)

and **1** injection
(2ND PRE-FILLED PEN OR SYRINGE OF THE 2-PACK)
every **2 weeks** thereafter

1 refill provides 4 weeks of maintenance therapy.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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

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.

Patients with Co-Morbid Asthma: Advise patients with atopic dermatitis or CRSwNP who have co-morbid asthma 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.

DUPIXENT® (dupilumab)

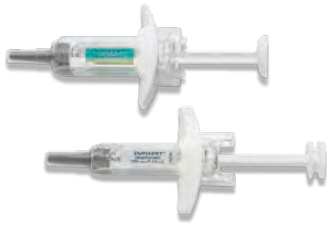
AT-HOME OR IN-OFFICE ADMINISTRATION OPTIONS

PRE-FILLED PEN (12+ YEARS)[1,2]

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

PRE-FILLED SYRINGE[1,3]

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



How to take DUPIXENT

- 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 using the pre-filled syringe or pen
  - In adolescents 12 years of age and older, it is recommended that DUPIXENT be administered by or under the supervision of an adult
  - The DUPIXENT pre-filled syringe should be given by a caregiver in children 6 to 11 years of age
  - Provide proper training to patients and/or caregivers on the preparation and administration of DUPIXENT prior to use according to the Instructions for Use
- 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
- 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 schedule
- 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 date

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS:

- **Atopic dermatitis:** The most common adverse reactions (incidence ≥1% at Week 16) in adult patients 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.

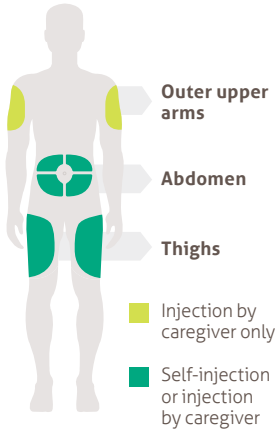
Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Specific to moderate-to-severe atopic dermatitis

- DUPIXENT can be used with or without topical corticosteroids. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only, such as the face, neck, and intertriginous and genital areas
- There is no requirement for initial lab testing or ongoing lab monitoring, according to the DUPIXENT Prescribing Information

Administer at different injection sites

- *Atopic dermatitis and asthma patients*: For the initial dose, administer each of the 2 injections at different injection sites
- 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



How DUPIXENT is supplied

DUPIXENT is available in cartons containing 2 pre-filled pens with hidden needle or 2 pre-filled syringes with needle shield. The pre-filled pen is designed to deliver 300 mg of DUPIXENT in a 2 mL solution. The pre-filled syringe is designed to deliver 300 mg of DUPIXENT in a 2 mL solution or 200 mg in a 1.14 mL solution.

DUPIXENT prescriptions can be filled at select retail pharmacies or through specialty pharmacies, which can ship medication directly to patients.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (cont'd):

- **Asthma:** The most common adverse reactions (incidence ≥1%) are injection site reactions, oropharyngeal pain, and eosinophilia.
- **Chronic rhinosinusitis with nasal polyposis:** The most common adverse reactions (incidence ≥1%) are injection site reactions, eosinophilia, insomnia, toothache, gastritis, arthralgia, and conjunctivitis.

DUPIXENT® (dupilumab)

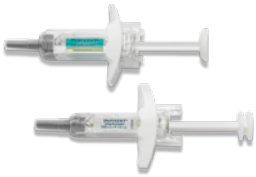
DUPIXENT OFFERS MULTIPLE ADMINISTRATION OPTIONS FOR YOU AND YOUR PATIENTS

AT-HOME OR IN-OFFICE ADMINISTRATION OPTIONS[1]

PRE-FILLED PEN (12+ YEARS)

Available in 300 mg

PRE-FILLED SYRINGE



Available in 300 mg and 200 mg

DUPIXENT MyWay® provides support to patients to help enable access to DUPIXENT

Nursing support

- Nurse educators take a patient-centric approach to providing tools, resources, and education that helps support patients with starting and staying on DUPIXENT
- Supplemental injection training in addition to the training you provide to your patients—either over the phone, virtually, or in person

Visit *DUPIXENTHCP.COM* for more information

IMPORTANT SAFETY INFORMATION

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.

Please click here for full Prescribing Information.

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

DUPIXENT® (dupilumab)

SANOFI GENZYME

REGENERON

DUP.20.07.0688 08/2020