## When Triple Inhaled Therapy is Not Enough

# A BREAKTHROUGH THERAPY IN COPD[1,a]


**INDICATION**

**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.**

**IMPORTANT SAFETY INFORMATION**

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

sanofi | REGENERON®

DUPIXENT® (dupilumab) Injection 300mg

[a]As designated by the US Food and Drug Administration (FDA).

**1.** DUPIXENT® (dupilumab) injection package insert.

US.DUP.24.02.0181 09/2024

**Please see Important Safety Information throughout and full Prescribing Information provided at this program.**

# Speaker Disclosure

- Regeneron Pharmaceuticals, Inc. and Sanofi are sponsoring this presentation
- Speakers are presenting on behalf of Regeneron and Sanofi and are being compensated by Regeneron and Sanofi for this presentation
- Speakers are presenting information that is consistent with FDA-approved prescribing information and applicable FDA regulations and practices
- The content contained in this presentation was jointly developed by Sanofi and Regeneron and is not eligible for continuing medical education (CME) credits

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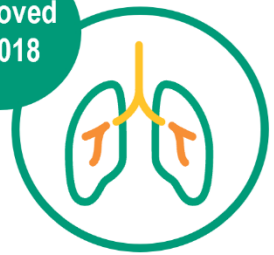
# DUPIXENT (dupilumab)

## ASTHMA

Approved in 2018



Moderate-to-severe eosinophilic phenotype

or OCS dependent

### #1 PRESCRIBED BIOLOGIC BY PULMONOLOGISTS FOR ASTHMA[1]

Limitations of Use: DUPIXENT is not indicated for the relief of acute bronchospasm or status asthmaticus.

## COPD

Now Approved

Inadequately controlled and an eosinophilic phenotype

### THE FIRST AND ONLY BIOLOGIC APPROVED IN COPD[2]

Limitations of Use: DUPIXENT is not indicated for the relief of acute bronchospasm.

***The Only Biologic Approved in Both Asthma and COPD***

**INDICATION**

**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.**

EOS, eosinophil; OCS, oral corticosteroid.

1. Data on file, Sanofi US. New to Brand Monthly Audit; data through June 2023. 2. DUPIXENT® (dupilumab) injection package insert.

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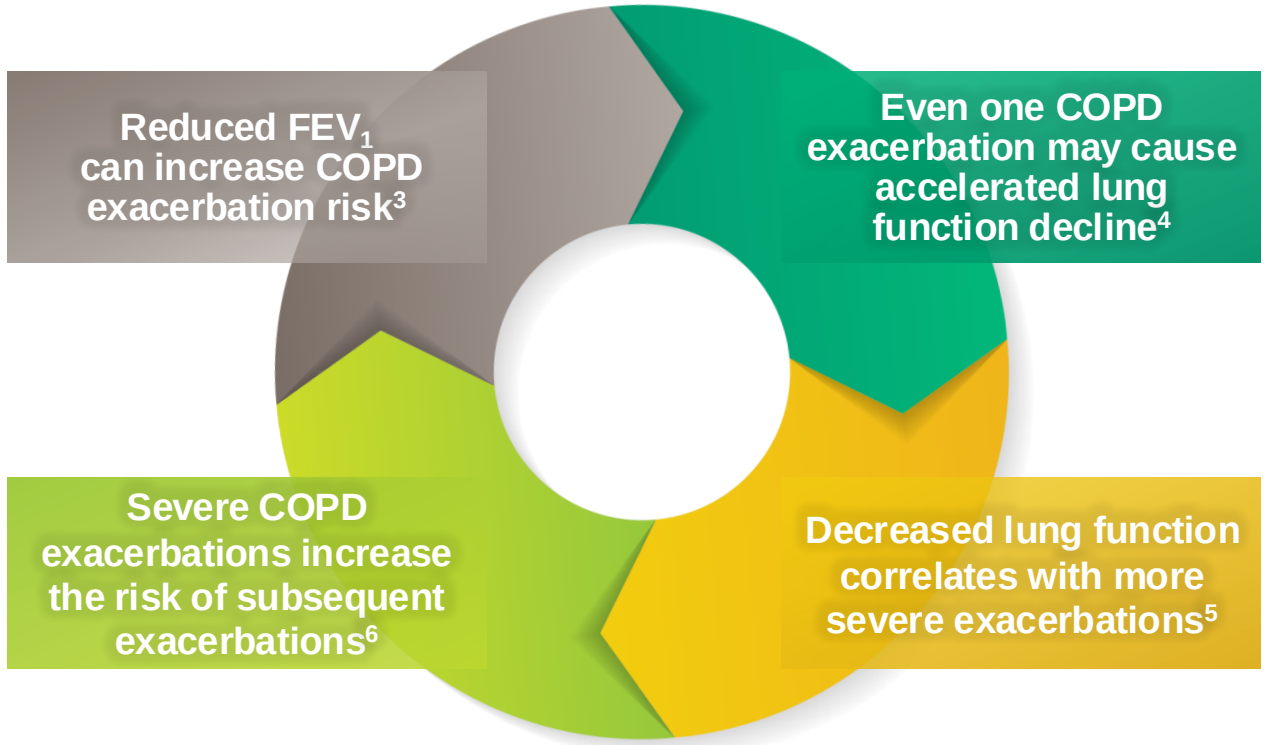
# Despite Triple Inhaled Therapy, Patients May Continue to Experience Exacerbations

## The progressive spiral of lung function decline and exacerbations[1,2]




**~50%**

**of COPD patients on triple inhaled therapy continued to experience moderate or severe exacerbations[7,a]**

[a]Results from a phase 3 randomized, double-blind, parallel-group multicenter trial. The primary objective was to evaluate the effects of double vs triple inhaled therapy on the rate of moderate or severe COPD exacerbations over 52 weeks. In individuals with a history of moderate or severe exacerbations, 47.3% of patients on triple inhaled therapy and 50.1% of patients on double inhaled therapy experienced one or more additional moderate or severe exacerbations in the subsequent 52 weeks. In individuals with a history of one or more severe exacerbations only, 51% of patients on triple inhaled therapy and 54.5% of patients on double inhaled therapy experienced one or more moderate or severe exacerbations in the following 52 weeks.

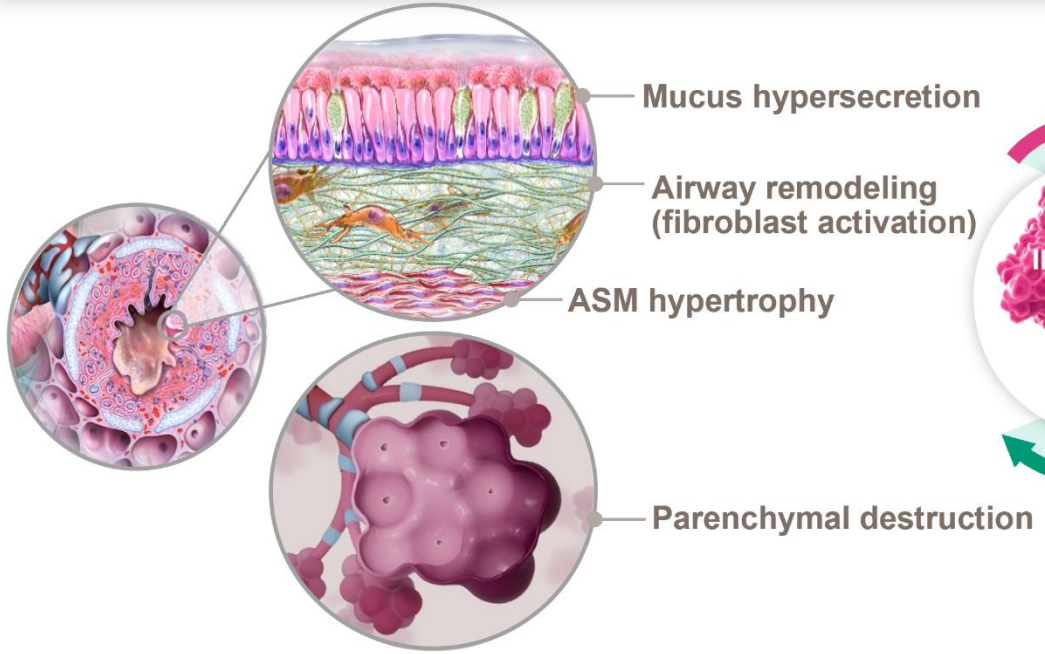
$FEV_1$, forced expiratory volume in 1 second.

**1.** Donaldson GC, et al. *Thorax*. 2002;57(10):847-852. **2.** Seemungal TA, et al. *Am J Respir Crit Care Med*. 2000;161(5):1608-1613. **3.** Hurst JR, et al. *Respir Res*. 2022;23(1):213. **4.** Halpin DMG, et al. *Respir Med*. 2017;128:85-91. **5.** Hurst JR, et al. *N Engl J Med*. 2010;363(12):1128-1138. **6.** Suissa S, et al. *Thorax*. 2012;67(11):957-963. **7.** Halpin DMG, et al. *Eur Respir J*. 2020;55(5):1901921.

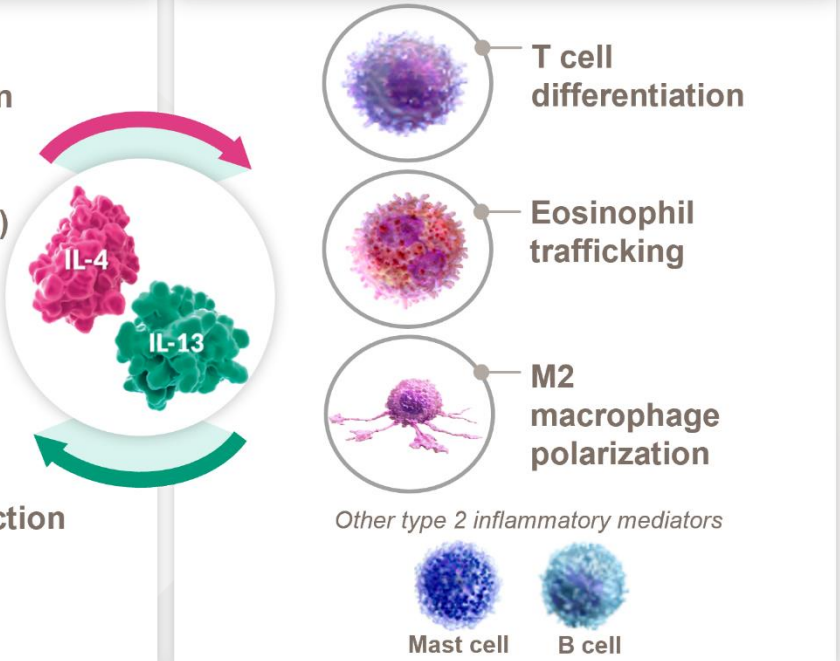
# DUPIXENT Is the First and Only Biologic Approved in COPD[1]


**OF PATIENTS WITH COPD MAY HAVE TYPE 2 INFLAMMATION AS INDICATED BY AN ELEVATED BLOOD EOS COUNT[2-6,b]**

## Local Inflammation[7,8]




## Systemic inflammation[7,8]




**DUPIXENT inhibits IL-4 and IL-13 signaling, two key drivers of type 2 inflammation in COPD[1,a]**

**[a]The mechanism of dupilumab action has not been definitively established.**

[a]Based on findings from 5 studies in COPD patients without asthma. Eosinophil levels used to define type 2 inflammation ranged from ≥300 cells/µL to ≥340 cells/µL (blood), ≥2% in induced sputum, or 3% in peripheral blood. Percentages of patients with type 2 inflammation ranged from 12.3% to ~40%.

ASM, airway smooth muscle; IL, interleukin.

**1.** DUPIXENT® (dupilumab) injection package insert. **2.** Oshagbemi O, et al. *COPD*. 2019;16(2):152-159. **3.** Casanova C, et al. *Eur Respir J*. 2017;50:1701162. **4.** Singh D, et al. *Eur Respir J*. 2014;44(6):1697-1700. **5.** Bafadhel M, et al. *Am J Respir Crit Care Med*. 2011;184(6):662-671. **6.** Oshagbemi OA, et al. *Am J Respir Crit Care Med.* 2017;195(10):1402-1404. **7.** Polverino F, Sin DD. *Eur Respir J.* 2024;63(5):2400150. **8.** Rabe KF, et al. *Am J Respir Crit Care Med.* 2023;208(4):395-405.

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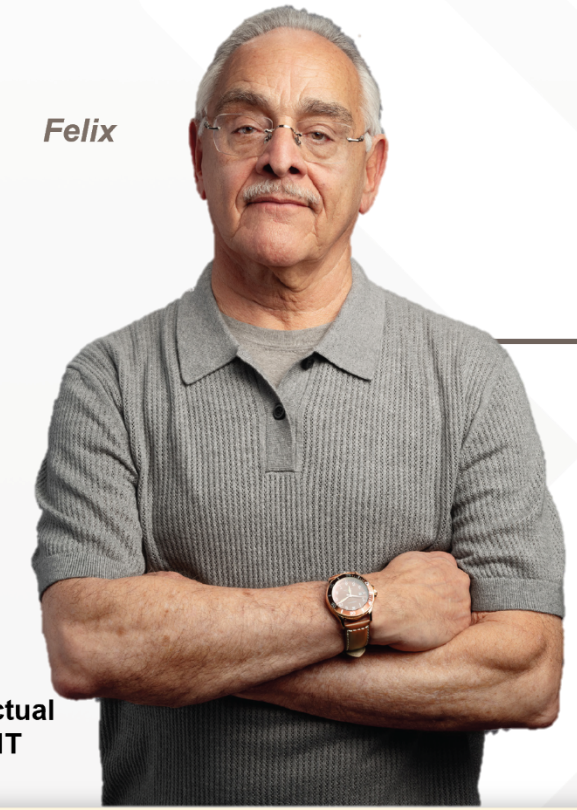
# DUPIXENT Can Help Patients Like Felix With Their COPD[1]

*Felix*



**Not an actual DUPIXENT patient.**

## CLINICAL PRESENTATION

*Despite being on triple inhaled therapy, he remains frustrated by his productive cough and experiences **ongoing symptoms**. His blood EOS levels were measured at over **360 cells/µL.***

## LAST OCS BURST: 2 MONTHS AGO

*He had **two exacerbations in the past year** that required treatment with OCS.*

## WHAT'S NEXT?

**An elevated blood eosinophil level (≥300 cells/µL) is recognized by the 2024 GOLD report as a clinically useful biomarker for identifying COPD with type 2 inflammation.[2]**

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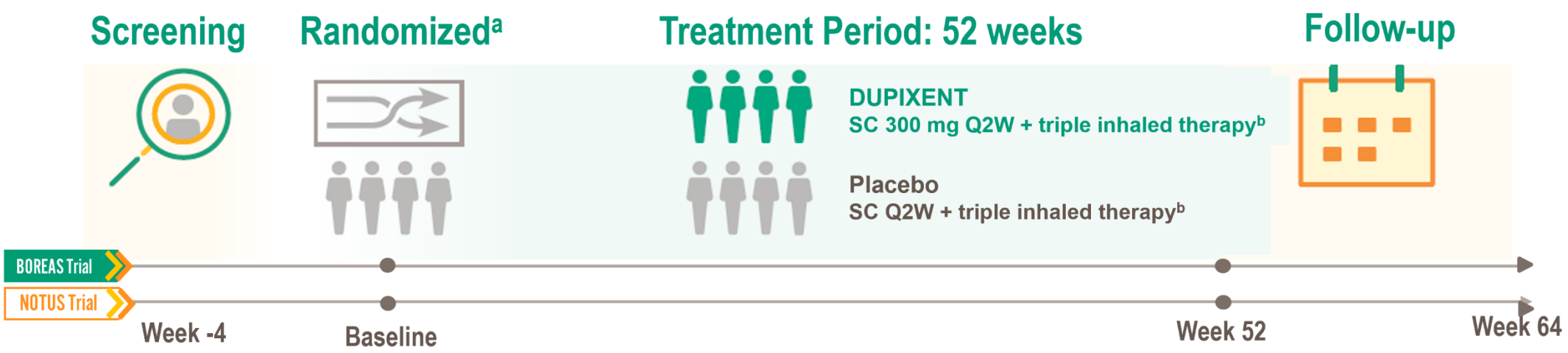
GOLD, Global Initiative for Chronic Obstructive Lung Disease.
**1.** DUPIXENT® (dupilumab) injection package insert. **2.** Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2024.

# DUPIXENT Was Studied in Two Phase 3 Clinical Trials With Over 1800 Patients

## BOREAS and NOTUS Clinical Study Designs[1]




### Select Enrollment Criteria

- Background triple inhaled therapy (ICS+LAMA+LABA) for 3 months prior to randomization with a stable dose of medication for ≥1 month prior to Visit 1; double inhaled therapy (LAMA+LABA) allowed if an ICS was contraindicated
- ≥2 moderate or ≥1 severe exacerbations within the year prior to screening, ≥1 exacerbation while the patient was on the SOC[c,d]
- Minimum blood EOS ≥300 cells/μL at screening
- Post-BD $FEV_1$/FVC ratio <0.7 and a post-BD $FEV_1$ % predicted >30% and ≤70%
- Chronic productive cough for at least 3 months in the past year in the absence of other known causes of chronic cough

Patients with a history of asthma were excluded

### Primary Endpoint

- **Annualized rate of moderate or severe COPD exacerbations from baseline to Week 52**

[a]1874 patients were enrolled in the BOREAS (N=939) and NOTUS (N=935) trials. [b]98% received ICS + LAMA + LABA in BOREAS and 99% in NOTUS. [c]SOC was triple inhaled therapy (LAMA + LABA + ICS). [d]Exacerbation severity was further defined as moderate if treatment with systemic corticosteroids and/or antibiotics was required, or severe if they resulted in hospitalization or observation for over 24 hours in an emergency department or urgent care facility.

BD, bronchodilator; FVC, forced vital capacity; ICS, inhaled corticosteroids; LABA, long-acting beta agonist; LAMA, long-acting muscarinic antagonist; Q2W, once every 2 weeks; SC, subcutaneous, SOC, standard of care.

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# Patient Characteristics at Baseline

## Select Demographics and Disease Characteristics at Baseline[1]

| | BOREAS Trial (N=939) | NOTUS Trial (N=935) |
|---|---|---|
| Mean age (years [±SD]) | 65.1 (8.1) | 65.0 (8.3) |
| Emphysema (%) | 32.6 | 30.4 |
| Mean smoking history (pack-years [±SD]) | 40.5 (23.4) | 40.3 (27.2) |
| Current smokers (%) | 30.0 | 29.5 |
| Background COPD medications at randomization: ICS/LAMA/LABA (%) | 97.6 | 98.8 |
| Mean number of moderate or severe[a] exacerbations in previous year (±SD) | 2.3 (1.0) | 2.1 (0.9) |
| Mean baseline blood eosinophil count (cells/µL [±SD])[b] | 401 (298) | 407 (336) |
| Mean percent predicted post-bronchodilator $FEV_1$ (% [±SD]) | 50.6 (13.1) | 50.1 (12.6) |

[a]Moderate exacerbations were exacerbations that were treated with either systemic corticosteroids and/or antibiotics. Severe exacerbations were exacerbations requiring hospitalization or observation for over 24 hours in an emergency department or urgent care facility. [b]Reported baseline eosinophil value was obtained within 4 weeks of screening value.

SD, standard deviation.

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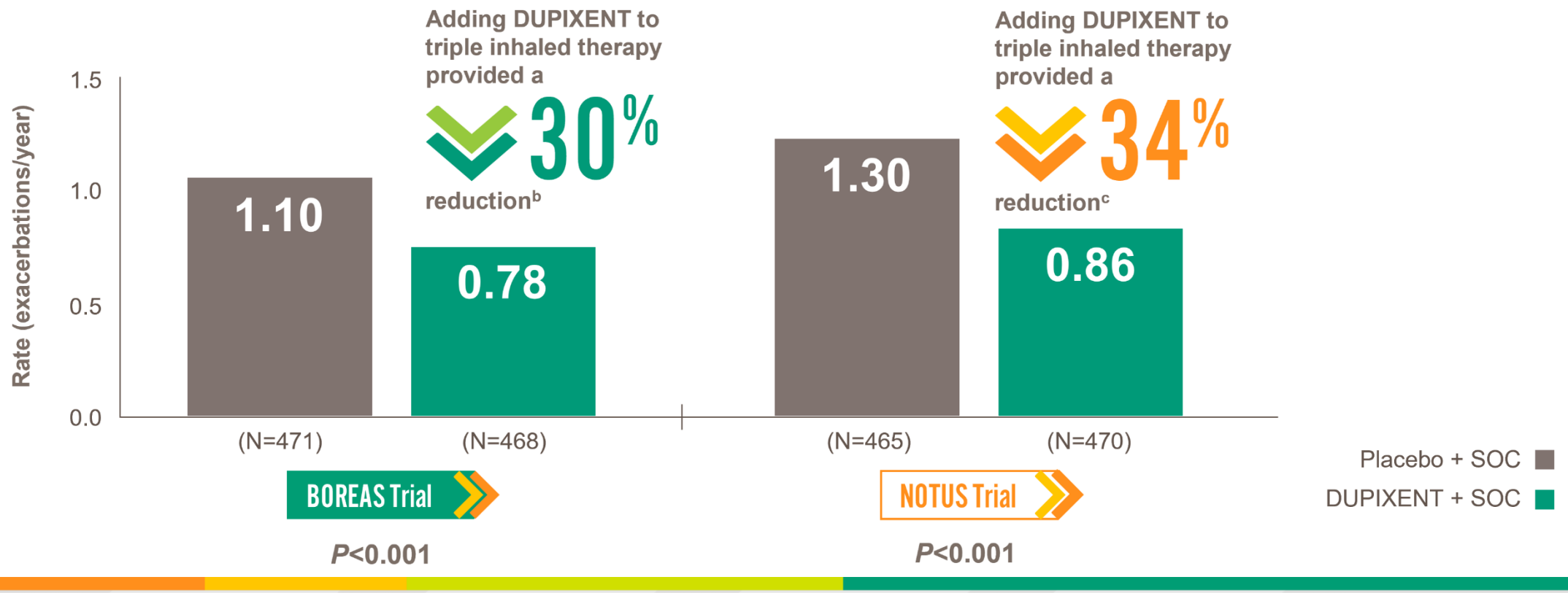
# DUPIXENT Significantly Reduced COPD Exacerbations

## Annualized rate of moderate or severe COPD exacerbations at Week 52 (primary endpoint)[1-3,a]




**SOC was triple inhaled therapy (LAMA + LABA + ICS).**

[a]Moderate exacerbations were defined as treated with either systemic corticosteroids and/or antibiotics. Severe exacerbations were defined as requiring hospitalization or observation for over 24 hours in an emergency department or urgent care facility or resulting in death. [b]Rate ratio vs placebo: 0.71 [95% CI: 0.58, 0.86]. [c]Rate ratio vs placebo: 0.66 [95% CI: 0.54, 0.82]. CI, confidence interval.

**1.** DUPIXENT® (dupilumab) injection package insert. **2.** Bhatt SP, et al. *N Engl J Med*. 2023;389(3):205-214. **3.** Bhatt SP, et al. *N Engl J Med*. 2024;390(24):2274-2283.

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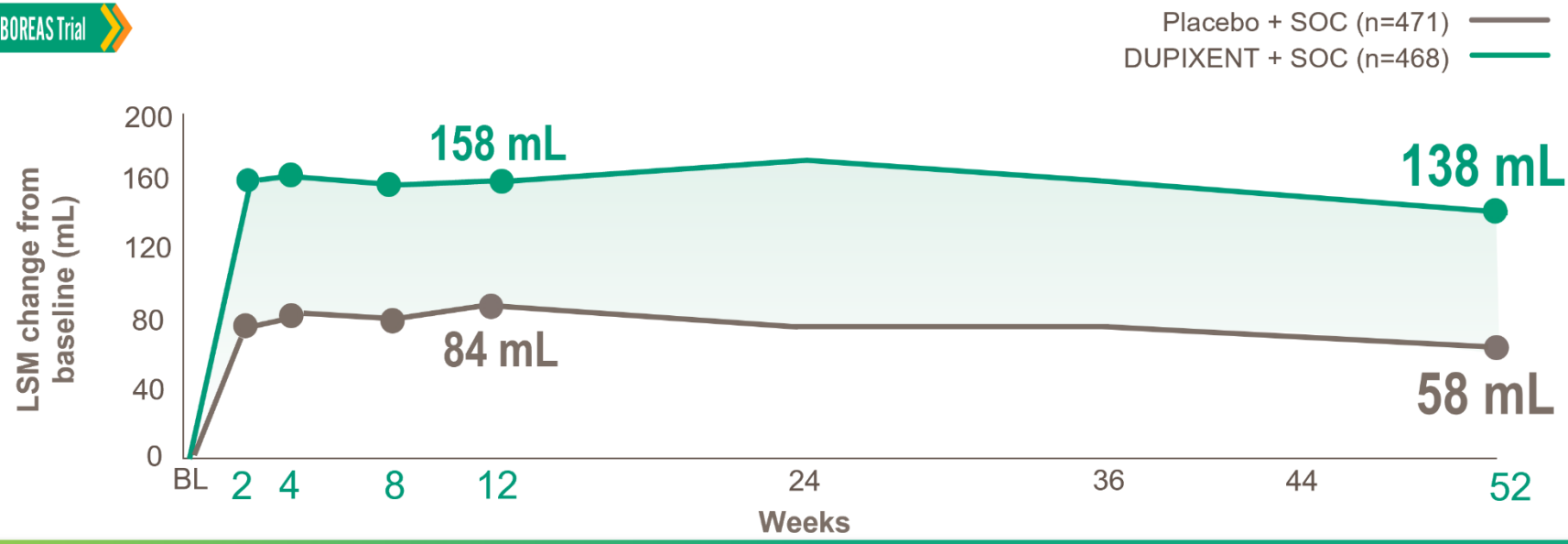
# DUPIXENT Showed Improvement in Lung Function

## Lung function improvement sustained through Week 52

### Change in post-BD $FEV_1$ from baseline at Week 12 and Week 52[1]

BOREAS Trial




NOTUS Trial

**Patients administered DUPIXENT + SOC saw numerical improvement in post-BD $FEV_1$ of 134 mL at Week 12 (n=470) and 127 mL at Week 52 (n=362), compared with 67 mL at Week 12 (n=465) and 59 mL at Week 52 (n=359) in patients receiving placebo + SOC (LSM change from baseline, ITT population).[1]**

### Change in pre-BD $FEV_1$[1-3]

**Significant improvements of similar magnitude were observed in change from baseline in pre-BD $FEV_1$ at Weeks 12 and 52 in subjects treated with DUPIXENT compared to placebo across the BOREAS and NOTUS trials.[1]**

**Post-BD results are descriptive. Definitive conclusions cannot be made.**
**SOC was triple inhaled therapy (LAMA + LABA + ICS).**

BD, bronchodilator, ITT, intent to treat; LSM, least square mean.


**1.** DUPIXENT® (dupilumab) injection package insert. **2.** Bhatt SP, et al. *N Engl J Med*. 2023;389(3):205-214. **3.** Bhatt SP, et al. *N Engl J Med*. 2024;390(24):2274-2283.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# DUPIXENT Improved COPD Patients' Daily Quality of Life

**BOREAS Trial**

## Significant improvement in patient-reported symptoms, everyday activities, and psychosocial impacts of COPD as measured by SGRQ[2,a]

**51%**

**of patients reported a clinically meaningful (≥4-point) improvement at Week 52 with DUPIXENT vs 43% for placebo**
**(n=939, OR: 1.44; [95% CI: 1.10, 1.89], *P*=0.009)[1,2,b]**

**NOTUS Trial**

**51% responder rate at Week 52 for subjects treated with DUPIXENT vs 47% for placebo (n=721, OR: 1.16; 95% CI: 0.86, 1.58)[1,3]**

**NOTUS results are descriptive. Definitive conclusions cannot be made.**

[a]The SGRQ is a 50-item questionnaire designed to measure and quantify health status in adult patients with chronic airflow limitation. [b]SOC was triple inhaled therapy (LAMA + LABA + ICS).
OR, odds ratio; SGRQ, St. George's Respiratory Questionnaire.

**1.** DUPIXENT® (dupilumab) injection package insert. **2.** Bhatt SP, et al. *N Engl J Med.* 2023;389(3):205-214. **3.** Bhatt SP, et al. *N Engl J Med.* 2024;390(24):2274-2283.

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# Demonstrated Safety Profile in COPD Through 52 Weeks[1]

| Adverse reaction | BOREAS and NOTUS | |
|---|---|---|
| | DUPIXENT 300 mg Q2W N=938 n (%) | Placebo N=934 n (%) |
| Viral Infection[a] | 133 (14.2) | 115 (12.3) |
| Headache | 73 (7.8) | 62 (6.6) |
| Nasopharyngitis | 73 (7.8) | 69 (7.4) |
| Back pain | 42 (4.5) | 29 (3.1) |
| Diarrhea[a] | 35 (3.7) | 30 (3.2) |
| Arthralgia | 29 (3.1) | 25 (2.7) |
| Urinary Tract Infection | 28 (3.0) | 18 (1.9) |
| Local Administration Reaction[a] | 26 (2.8) | 6 (0.6) |
| Injection Site Reaction | 11 (1.2) | 2 (0.2) |
| Rhinitis | 24 (2.6) | 17 (1.8) |
| Eosinophilia[b] | 22 (2.3) | 7 (0.7) |
| Toothache | 20 (2.1) | 11 (1.2) |
| Gastritis | 19 (2) | 7 (0.7) |

[a]Consists of multiple similar terms. [b]Eosinophilia was defined as blood eosinophils ≥3,000 cells/μL or deemed by the investigator to be an adverse event. None met the criteria for serious eosinophilic conditions.

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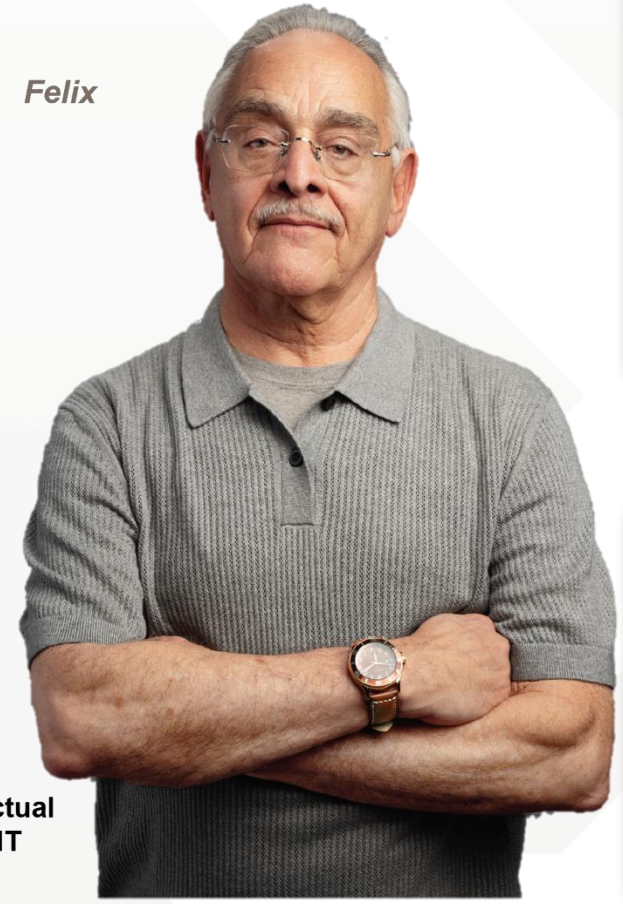
# Felix Started DUPIXENT Every Two Weeks With the Option of At-Home Administration

*Felix*



**Not an actual DUPIXENT patient.**

## No Loading Dose[1]

ADULTS — 300 mg — EVERY 2 WEEKS

1 pre-filled pen or syringe[a]

## TWO ADMINISTRATION OPTIONS FOR YOUR PATIENTS

### DUPIXENT Pre-filled pen[1,b]

- Single-press auto-injector
- A clear 2-step process
- Visual and audible feedback
- Compact and convenient to carry
- Hidden needle


### DUPIXENT Pre-filled syringe[1,b]

- Manual control of ejection speed
- Finger grip for comfort
- Visual confirmation of injection delivery
- Needle shield
- Easy-to-carry format

[a]300 mg = 2 mL solution. [b]A patient may self-inject DUPIXENT—or a caregiver may administer DUPIXENT—after training has been provided by a healthcare provider on proper subcutaneous injection technique using the pre-filled syringe or pen. It is important to provide proper training to patients and/or caregivers on the preparation and administration of DUPIXENT prior to use.

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# A Breakthrough Therapy in COPD[a]

## DUPIXENT has the ability to:


Not an actual DUPIXENT patient.

### REDUCE
**EXACERBATIONS**

Up to

**34%**

**Moderate or severe exacerbation reduction at Week 52**

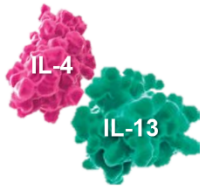
(annualized rate)(primary endpoint)[1,b,c]

### IMPROVE
**PATIENTS' BREATHING AND QUALITY OF LIFE**

**Lung Function**
(measured by pre- and post-bronchodilator $FEV_1$)

**Quality of Life**
(measured by SGRQ)

### TARGET
**TWO OF THE KEY DRIVERS OF TYPE 2 INFLAMMATION**




**IL-4 and IL-13 are two of the key drivers of local and systemic inflammation[1,d]**

**The most common adverse reactions (incidence ≥2%) in patients with COPD are viral infection, headache, nasopharyngitis, back pain, diarrhea, arthralgia, urinary tract infection, local administration site reactions, rhinitis, eosinophilia, toothache, and gastritis.[1]**

**[d]The mechanism of dupilumab action has not been definitively established.**

[a]As designated by the US Food and Drug Administration (FDA). [b]Moderate exacerbations were exacerbations that resulted in treatment with a systemic glucocorticoid, an antibiotic agent, or both. Severe exacerbations were exacerbations that led to hospitalization, or an emergency department visit or that resulted in death. [c]At Week 52 in the NOTUS trial, patients treated with DUPIXENT + SOC (n=470) experienced an annualized rate of 0.86 moderate or severe exacerbations vs 1.30 for those treated with placebo + SOC (n=465). Rate ratio vs placebo was 0.66 (95% CI: 0.54, 0.82) (*P*<0.001; primary endpoint). At Week 52 in the BOREAS trial, patients administered DUPIXENT + SOC (n=468) experienced 30% reduction (0.78 vs 1.10) in moderate or severe exacerbations vs placebo + SOC (n=471) (rate ratio: 0.71 [95% CI: 0.58, 0.86]).[1-3]

**1.** DUPIXENT® (dupilumab) injection package insert. **2.** Bhatt SP, et al. *N Engl J Med.* 2023;389(3):205-214. **3.** Bhatt SP, et al. *N Engl J Med*. 2024;390(24):2274-2283.

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# Important Safety Information (cont'd)

## 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 COPD subjects who received DUPIXENT versus placebo. Conjunctivitis and keratitis have been reported with DUPIXENT in postmarketing settings. Some patients reported visual disturbances (e.g., blurred vision) associated with conjunctivitis or keratitis. Advise patients or their caregivers 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.

**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. 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, and/or neuropathy presenting in their patients with eosinophilia. Cases of eosinophilic pneumonia were reported in adult subjects who participated in the asthma development program and cases of vasculitis consistent with EGPA have been reported with DUPIXENT in adult subjects who participated in the asthma development program as well as in adult subjects with co-morbid asthma in the chronic rhinosinusitis with nasal polyposis development program. A causal association between DUPIXENT and these conditions has not been established.

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# Important Safety Information (cont'd)

## WARNINGS AND PRECAUTIONS (cont'd)

**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.

**Arthralgia:** Arthralgia has been reported with 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 the symptoms persist or worsen, consider rheumatological evaluation and/or discontinuation of DUPIXENT.

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# Important Safety Information (cont'd)

## WARNINGS AND PRECAUTIONS (cont'd)

**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.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.

## ADVERSE REACTIONS:

**Most common adverse reactions are:**

- **Asthma:** (incidence ≥1%): injection site reactions, oropharyngeal pain, and eosinophilia.
- **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.

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# Important Safety Information (cont'd)

## 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.

IgG, immunoblogulin G.

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# The Only Biologic Approved in Both Asthma and COPD

## ASTHMA

**Moderate-to-severe eosinophilic phenotype or OCS dependent[1]**

*Asthma Phenotypes*

- Uncontrolled asthma with **elevated blood EOS (≥150 cells/µL)** as evidence of type 2 inflammation
- Uncontrolled asthma with type 2 inflammation requiring **multiple OCS bursts**
- **Children (6-11 years) with uncontrolled asthma** and elevated blood EOS (≥150 cells/µL) as evidence of type 2 inflammation

Limitations of Use: DUPIXENT is not indicated for the relief of acute bronchospasm or status asthmaticus.

## COPD

**Inadequately controlled and an eosinophilic phenotype[1]**

*Patient Characteristics*

- **Symptomatic** while receiving triple inhaled therapy
- Two moderate **COPD exacerbations** in the past year requiring treatment with OCS
- **Elevated blood EOS levels (≥300 cells/µL)** as evidence of type 2 inflammation

Limitations of Use: DUPIXENT is not indicated for the relief of acute bronchospasm.

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# THANK YOU

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## GETTING YOUR PATIENTS STARTED WITH DUPIXENT

*DUPIXENT MyWay*® Provides Support to Patients to Help Enable Access to DUPIXENT

**Nursing Support**

**Coverage Support**

**Patient Access Support**

**Call 1-844-DUPIXEN(T) or visit DUPIXENTHCP.COM/MYWAY for more information on program enrollment**

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US.DUP.24.02.0181 09/2024