DUPIXENT® (dupilumab) Injection 300mg

FOR ADULTS WITH
PN
PRURIGO NODULARIS

"I'VE PICKED AND SCRATCHED AT THE PERSISTENT ITCH AND UNSIGHTLY NODULES FOR 10+ YEARS. NOW WITH DUPIXENT, I HAVE IT UNDER CONTROL."

MEET JOSEPH

Age 54

Not an actual DUPIXENT patient.

HIS STORY

Joseph had struggled with prurigo nodularis (PN) for more than 10 years and was referred to a dermatologist by his primary care physician. Topical therapies did not work. Joseph needed another approach to help reduce his itch and clear his skin of nodules.

INDICATION

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.

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 Important Safety Information throughout and click here for full Prescribing Information.

HIS SIGNS AND SYMPTOMS

- Between 50 to 70 nodules on his trunk and arms
- Intense itch-scratch cycle that resulted in nodules and scarring
- Bothersome itch, even where nodules were not present

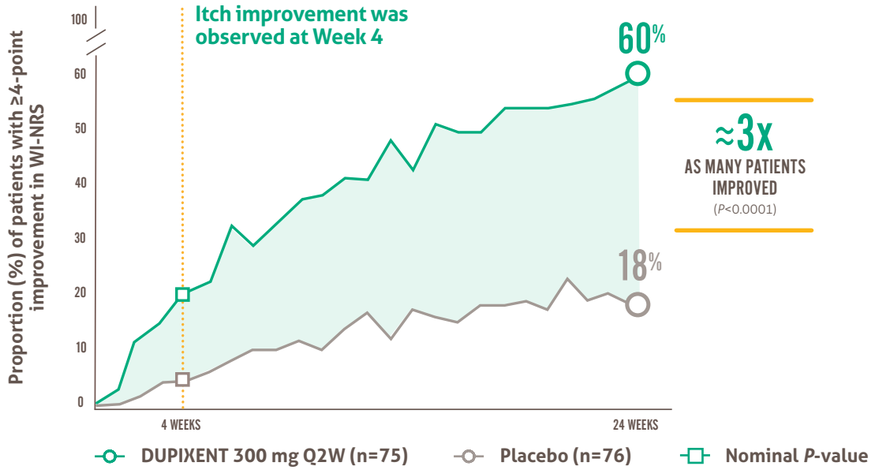
HIS TREATMENT AND GOALS

- Previous management approaches have been unsuccessful
- A therapy to help treat his itch and reduce nodules is needed

PRIME

ITCH IMPROVEMENT SEEN AS EARLY AS WEEK 4

A significantly higher proportion of DUPIXENT patients achieved meaningful itch improvement at Week 24 (primary endpoint)[1,2,a]



[a]Baseline WI-NRS scores: 8.6 (SD, 0.9) for DUPIXENT, 8.3 (SD, 1.1) for placebo.

- A nominal difference was observed at Week 4 (**19%** with DUPIXENT vs **4%** with placebo)[2]

PRIME2

- A nominal difference was observed at Week 11 (**33%** with DUPIXENT vs **17%** with placebo) with a significantly greater proportion of DUPIXENT patients achieving a meaningful response at Week 12 (**37%** with DUPIXENT vs **22%** with placebo; primary endpoint). At Week 24, **58%** of DUPIXENT patients achieved significant itch relief vs **20%** with placebo; secondary endpoint[2]

Definitive conclusions cannot be made for results earlier than at 24 weeks in PRIME and at timepoints other than weeks 12 and 24 in PRIME2. Data were not multiplicity-controlled.

TRIAL DESIGN: The PN development program included two 24-week randomized, double-blind, placebo-controlled, multicenter, parallel-group trials (PRIME and PRIME2) in 311 adult subjects 18 years of age and older with pruritus (WI-NRS ≥7 on a scale of 0 to 10) and ≥20 nodular lesions. PRIME and PRIME2 assessed the effect of DUPIXENT on pruritus improvement as well as its effect on PN lesions. In these two trials, subjects received either subcutaneous DUPIXENT 600 mg (two 300 mg injections) on Day 1, followed by 300 mg Q2W for 24 weeks, or matching placebo.[1,2]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

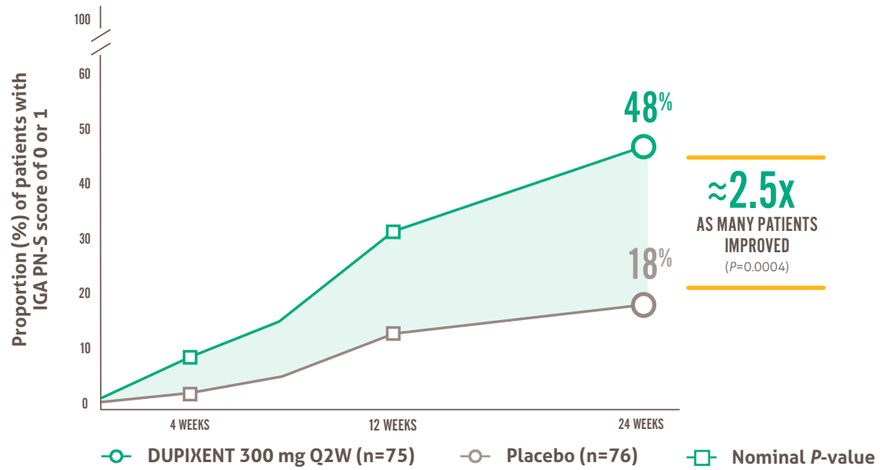
Conjunctivitis and Keratitis: Conjunctivitis occurred more frequently in prurigo nodularis subjects who received DUPIXENT versus placebo; these subjects recovered or were recovering during the treatment period. There were no cases of keratitis reported in the PN development program. Conjunctivitis and keratitis have been reported with DUPIXENT in postmarketing settings, with some patients reporting visual disturbances (e.g., blurred vision). 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.

PRIME

ACHIEVE SIGNIFICANT NODULE CLEARANCE

DUPIXENT patients achieved significant reduction in nodules vs placebo at Week 24 (secondary endpoint)[1,2,b]



[b]Baseline IGA PN-S scores: 3.3 (SD, 0.5) for DUPIXENT, 3.3 (SD, 0.5) for placebo.

- A nominal difference was observed at Week 4 (**9%** with DUPIXENT vs **1%** with placebo) and at Week 12 (**32%** with DUPIXENT vs **12%** with placebo)[2]

PRIME2

- At Week 4, **8%** of patients treated with DUPIXENT vs **6%** with placebo, had nodule clearance. A significantly greater proportion of DUPIXENT patients achieved nodule clearance at Week 12 (**26%** with DUPIXENT vs **12%** with placebo) and Week 24 (**45%** with DUPIXENT vs **16%** with placebo)[2]

Definitive conclusions cannot be made for results earlier than at 24 weeks in PRIME and at timepoints other than Week 12 and 24 in PRIME2. Data were not multiplicity-controlled.

DUPIXENT EFFICACY DEMONSTRATED CONSISTENT TREATMENT EFFECT ACROSS STUDY POPULATION, INCLUDING THOSE WITH HISTORY OF ATOPY[1]

TRIAL ENDPOINTS: The WI-NRS consists of a single item, rated on a scale from 0 ("no itch") to 10 ("worst imaginable itch"). Subjects were asked to rate the intensity of their worst pruritus (itch) over the past 24 hours using this scale. The IGA PN-S measures the approximate number of nodules using a 5-point scale from 0 (clear) to 4 (severe).[1]

IGA PN-S, Investigator's Global Assessment PN-Stage; Q2W, once every 2 weeks; SD, standard deviation; WI-NRS, Worst Itch Numeric Rating Scale.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

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.

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

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DEMONSTRATED SAFETY PROFILE IN PRURIGO NODULARIS[1]

Most common adverse reactions (≥2%, pooled safety data across PRIME and PRIME2)[1]

ADVERSE REACTION (AR)	DUPIXENT 300 mg Q2W (n=152)	PLACEBO (n=157)
Nasopharyngitis[a]	5%	2%
Conjunctivitis[b]	4%	1%
Herpes Infection[c]	3%	0%
Dizziness[d]	3%	1%
Myalgia[e]	3%	1%
Diarrhea	3%	1%

[a]Nasopharyngitis includes pharyngitis.
[b]Conjunctivitis includes conjunctivitis and allergic conjunctivitis.
[c]Herpes infection includes oral herpes, genital herpes simplex, herpes zoster, and ophthalmic herpes zoster.
[d]Dizziness includes dizziness postural, vertigo, and vertigo positional.
[e]Myalgia includes musculoskeletal pain and musculoskeletal chest pain.

- **DISCONTINUATION DUE TO ADVERSE EVENTS (AEs):** 0% with DUPIXENT vs 3% with placebo[1]
  - Patients should discontinue DUPIXENT if a clinically significant hypersensitivity reaction occurs or until a parasitic (helminth) infection resolves in a patient who does not respond to anti-helminth treatment

IMPORTANT CONSIDERATIONS[1]

NO BOXED WARNING

NOT METABOLIZED THROUGH THE LIVER OR EXCRETED THROUGH THE KIDNEYS

- No known drug-to-drug interactions

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

OTHER ATTRIBUTES[1]

DUPIXENT IS NOT AN IMMUNOSUPPRESSANT

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

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.

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.

ONE DOSE EVERY 2 WEEKS AFTER INITIAL LOADING DOSE

ONE DOSAGE REGIMEN IN ADULTS[1]

18+ YEARS

Initial loading dose:
600 mg
2 x 300 mg

Followed by:
300 mg Q2W
1 x 300 mg

- DUPIXENT is administered by subcutaneous injection and intended for use under the guidance of a healthcare provider[1]
- Rotate injection site with each injection[1]
- Provide proper training to patients and/or caregivers on the preparation and administration of DUPIXENT prior to use, according to the Instructions for Use[1]
- Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with DUPIXENT[1]
- **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[1]

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥2%) in patients with prurigo nodularis 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.

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References: 1. DUPIXENT Prescribing Information. **2.** Data on file, Regeneron Pharmaceuticals, Inc.

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SIGNIFICANT ITCH IMPROVEMENT AND NODULE CLEARANCE WITH THE FIRST AND ONLY FDA-APPROVED TREATMENT IN PRURIGO NODULARIS[1,2]

Not an actual DUPIXENT patient.

Significant improvement in itch and nodule clearance[1,2]

≈3x as many patients had significantly reduced itch in PRIME at Week 24 (60% with DUPIXENT vs 18% with placebo; *P*<0.0001) [primary endpoint]

≈2.5x as many patients achieved significant nodule clearance in PRIME at Week 24 (48% with DUPIXENT vs 18% with placebo; *P*=0.0004) [secondary endpoint]

A demonstrated safety profile in 2 PN trials[1]

- Most common adverse reactions (≥2%) were nasopharyngitis, conjunctivitis, herpes infection, dizziness, myalgia, and diarrhea
- No patients treated with DUPIXENT discontinued the study due to AEs vs 3% with placebo
  - Patients should discontinue DUPIXENT if a clinically significant hypersensitivity reaction occurs or until a parasitic (helminth) infection resolves in a patient who does not respond to anti-helminth treatment

DUPIXENT is not an immunosuppressant[1]

INDICATION

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.

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SEE HOW REAL CHANGE IS ACHIEVABLE IN ITCH AND NODULE CLEARANCE FOR OTHER PATIENTS LIKE JOSEPH

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