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Dupilumab for prurigo nodularis: real-world outcomes up to 104 weeks from the Dupilumab Italian Prurigo Nodularis (DUPItaPN) study

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Abstract

Background **Prurigo nodularis (PN) is a chronic, intensely pruritic skin disorder that markedly impairs quality of life. Dupilumab, an interleukin-4Rα antagonist, is approved for moderate-to-severe PN, but long-term real-world evidence remains limited.**

Objectives **To evaluate the long-term effectiveness and safety of dupilumab in adults with PN, including those with multiple comorbidities, in a real-world multicentre setting.**

Methods **Clinical data were collected from 26 Italian dermatology centres [the Dupilumab Italian Prurigo Nodularis (DUPItaPN) study]. Adults with PN refractory to topical therapies and/or phototherapy, and/or prior systemic treatments who received dupilumab for a minimum treatment duration of 12 weeks were included. Outcomes routinely assessed in practice – Worst Itch (WI) Numeric Rating Scale (NRS) (WI-NRS), Investigator Global Assessment for PN-Stage (IGA PN-S), Sleep-NRS, Skin Pain-NRS and Dermatology Life Quality Index (DLQI) – were analysed at baseline and weeks 12, 24, 52, 76 and 104. Main endpoints were ≥ 4-point WI-NRS reduction and IGA PN-S 0/1 status. Predictors of response and safety were also evaluated.**

Results **In total, 543 patients [mean age 65.7 (SD 15.8) years; 63.7% (346/543) female] were included. Dupilumab induced rapid and sustained improvements: mean WI-NRS decreased from 8.69 (SD 1.41) to 2.67 (SD 2.59) at week 24 and to 1.72 (SD 2.44) at week 104 ($P < 0.001$); ≥ 4-point WI-NRS reduction was achieved by 78.6% (408/519) and by 86.9% (258/297) of patients at 24 and 104 weeks, respectively; and IGA PN-S 0/1 achieved by 62.8% (326/519) and 81.1% (241/297) of patients at 24 and 104 weeks. DLQI improved from 17.40 (SD 6.94) to 2.57 (SD 4.89) ($P < 0.001$). Higher baseline WI-NRS predicted better outcomes, whereas psychiatric comorbidities and prior tricyclic antidepressant use predicted lower response. Dupilumab was well tolerated; discontinuation because of adverse events occurred in 2.9% (16/543), with no cancer progression or viral reactivation.**

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Conclusions **Dupilumab provided sustained, clinically meaningful benefits and a favourable safety profile over 104 weeks, supporting its role as a long-term treatment for moderate-to-severe PN, including in older adults and patients with comorbidities.**

What is already known about this topic?

- Prurigo nodularis (PN) is a chronic, intensely itchy skin disorder that greatly affects quality of life.
- Dupilumab is approved for moderate-to-severe PN, but real-world long-term data, especially in patients with multiple comorbidities, are limited.

What does this study add?

- Dupilumab showed rapid, sustained improvement in itch, lesions, sleep, pain and quality of life up to 104 weeks, with good safety even in older adults and patients with comorbidities.

Prurigo nodularis (PN), or nodular prurigo, is a chronic inflammatory skin disorder characterized by persistent pruritus and indurated nodules lasting ≥ 6 weeks.[1] These symptoms severely impair patients' quality of life and mental health.[2] Epidemiological studies report a prevalence of 6.5–111.0 per 100 000 (median 32.7) and an incidence of 2.9–20 per 100 000 person-years.[3] PN is strongly associated with psychiatric, endocrine, cardiovascular, renal diseases and malignancies, resulting in a higher comorbidity burden than other chronic dermatoses.[4] Anxiety, depression and suicidal ideation are particularly frequent.[5]

The pathophysiology of PN is multifactorial and incompletely understood, involving neuronal sensitization, dermal fibrosis and a self-perpetuating itch–scratch cycle. Given this complexity, therapy must balance efficacy and safety, especially in patients with comorbidities such as hypertension or renal impairment, and minimize drug interactions.[6]

Although individualized treatment based on disease severity, impact on quality of life and comorbidities remains essential, recent expert consensus and clinical practice guidelines now outline structured therapeutic options for PN.[7] In patients with mild cases, topical corticosteroids and calcineurin inhibitors remain first-line options.[8] For moderate-to-severe or refractory disease, systemic agents such as gabapentinoids, antidepressants, sedating antihistamines or short-term corticosteroids may be used, although efficacy is limited and long-term safety concerns persist. Phototherapy, immunosuppressants and neuromodulators represent additional, yet often suboptimal, alternatives.[9,10]

A major advance in PN therapy was the development of dupilumab, a fully human monoclonal antibody that binds the IL-4 receptor α subunit (IL-4Rα), thereby inhibiting signalling of both interleukin (IL)-4 and IL-13. By blocking these key type 2 inflammatory pathways, dupilumab reduces the activation of downstream Janus kinase–signal transducer and activator of transcription pathways, limits the recruitment of inflammatory cells and disrupts the itch–scratch cycle, leading to both decreased pruritus and improvement of skin lesions.[11] In 2022, dupilumab became the first systemic therapy approved by the US Food and Drug Administration and European Medicines Agency for adults with moderate-to-severe PN, based on the LIBERTY-PN PRIME and PRIME2 phase III trials ($n = 151$ and $n = 160$, respectively).[12–15] In these studies, dupilumab achieved significantly higher Worst Itch (WI) Numeric Rating Scale (NRS) (WI-NRS) response rates at week 24 vs. placebo (60.0% vs. 18.4% in PRIME; 57.7% vs. 19.5% in PRIME2) and greater reductions in nodule counts compared with placebo.

Real-world studies have since confirmed dupilumab's short- and mid-term effectiveness in PN across various populations.[16–18] However, evidence on long-term outcomes and large-scale safety remains limited. To address this gap, we conducted a multicentre Italian study to evaluate the long-term effectiveness and safety of dupilumab in adult patients with PN – the Dupilumab Italian Prurigo Nodularis (DUPItaPN) study.

Patients and methods

Study design

The systematic data collection was conducted across 26 Italian dermatology centres (Appendix S1; see Supporting Information) to describe the long-term use of dupilumab in patients with PN, including those with relevant comorbidities. This retrospective, multicentre observational study adopted a predefined follow-up schedule up to week 104, with data locked in August 2025. Because patients started dupilumab at different times, the dataset reflects a cross-sectional snapshot of treatment exposure and clinical outcomes at the time of data closure.

Adult patients (≥ 18 years) with a diagnosis of PN, defined by chronic pruritus lasting > 6 weeks, signs of repeated scratching, and the presence of pruritic nodules, were routinely treated with dupilumab in outpatient settings according to clinical judgement.[1] Only patients with a minimum treatment duration of 12 weeks were included, ensuring sufficient treatment exposure. Patients with end-stage chronic kidney disease, severe hepatic impairment or uncontrolled diabetes were excluded. No formal washout period was defined. Eligibility required lesions persisting for ≥ 3 months, treatment failure of topical therapies and/or phototherapy, ≥ 20 nodules and WI-NRS ≥ 7. Dupilumab was administered according to the Summary of Product Characteristics.[11]

Data about the patients treated with dupilumab, including demographic and clinical characteristics, history of atopic dermatitis or other atopic conditions, age at onset of atopic dermatitis, disease duration, comorbidities and details of previous and ongoing therapies, were collected. Disease severity was assessed using validated instruments, including the WI-NRS[19] (range 0–10), the

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Investigator Global Assessment for PN-Stage[20] (IGA PN-S, range 0 = clear to 4 = severe, ≥ 100 nodules), the Sleep-NRS[21] and Skin Pain-NRS[22] (both range 0–10) and the Dermatology Life Quality Index (DLQI, range 0–30). These measures were recorded at baseline and at follow-up visits (weeks 12, 24, 52, 76 and 104). Where available, laboratory parameters such as total IgE levels (kU L–1), lactate dehydrogenase (U L^{-1}) and eosinophil count ($\times 10^9$ L^{-1}) were also collected at baseline and during follow-up.

The primary measures of interest were the proportions of patients achieving a reduction of ≥ 4 points in WI-NRS and those reaching an IGA PN-S score of 0 or 1 during follow-up up to week 104. Additional analyses examined potential factors associated with clinical response. Safety was evaluated by describing adverse events and reasons for treatment discontinuation as routinely reported at each participating centre. This study used aggregated, fully anonymized data that were collected as part of routine clinical care and provided by participating centres in nonidentifiable, aggregate form. The dataset cannot be linked to individual patients; therefore, in accordance with applicable institutional policies and national regulations, formal ethics committee approval and individual informed consent were not required.

Statistical analysis

Continuous variables were expressed as mean (SD), and categorical variables as numbers and percentages. Missing data were handled using the last observation carried forward method. The Shapiro–Wilk test was applied to assess the distribution of continuous variables. Longitudinal comparisons were made using the Friedman test for repeated measures, and correlations between baseline IgE levels and clinical indices were assessed using Spearman's rank correlation coefficient. Univariate and multivariate analyses were conducted to explore whether baseline characteristics influenced the likelihood of achieving a ≥ 4-point WI-NRS reduction or an IGA PN-S score of 0 or 1. Statistical significance was set at $P < 0.05$, and all analyses were performed using Stata 11.2 software (StataCorp LP Inc., College Station, TX, USA).

Results

Baseline characteristics of dupilumab-treated patients

Data were collected from 543 patients treated with dupilumab monotherapy for ≥ 12 weeks. At the time of analysis, 519 patients had reached week 24, 417 week 52, 353 week 76 and 297 week 104. Baseline demographic characteristics are summarized in Table 1. The study population was predominantly female (63.7%, 346/543), with a mean age of 65.7 (SD 15.8) years and a mean body mass index of 26.7 (SD 3.2). The mean disease duration was 8.9 (SD 14.1) years, and 21.0% (114/543) of patients reported a history of smoking. A history of atopic dermatitis was present in 32.6% ($n = 177$) of 543 patients, allergic rhinitis in 17.9% ($n = 97$), asthma in 10.5% ($n = 57$) and allergic conjunctivitis in 5.3% ($n = 29$).

The most frequent systemic comorbidities were hypertension (42.9%, 233/543), dyslipidaemia and cardiovascular disease. Notably, 36 patients had a past or current malignancy, 23 had chronic kidney disease, 14 had a history of hepatitis B or C infection and 6 were HIV-positive and receiving therapy. Previous treatments most often included systemic corticosteroids (43.1%, 232/543), and approximately a quarter of patients had received systemic immunosuppressants or antidepressants. No patient received concomitant topical or systemic therapies for PN during the study period, as dupilumab was administered as monotherapy.

Table 1 Baseline clinical characteristics of patients with prurigo nodularis undergoing dupilumab therapy

Characteristics	Participants ($N = 543$)
Female/male	346 (63.7)/197 (36.3)
Age (years), mean (SD)	65.7 (15.8)
BMI (kg m^{-2}), mean (SD)	26.7 (3.2)
History of smoking	114 (21.0)
Age at onset (years), mean (SD)	56.6 (19.1)
Disease duration (years), mean (SD)	8.9 (14.1)
Atopic comorbidities	
Atopic dermatitis	177 (32.6)
Allergic rhinitis,	97 (17.9)
Asthma	57 (10.5)
Allergic conjunctivitis	29 (5.3)
Comorbidities	
Hypertension	233 (42.9)
Dyslipidaemia	96 (17.7)
Cardiovascular disorders	92 (16.9)
Psychiatric comorbidities	89 (16.4)
Diabetes	79 (14.5)
Thyroid disorders	53 (9.8)
Previous or current carcinoma	36 (6.6)
Chronic renal failure	23 (4.2)
Previous or chronic HCV/HBV infection	14 (2.6)
HIV infection	6 (1.1)
Previous systemic therapy	
Systemic steroid	232 (42.7)
Antihistamines	130 (23.9)
Tricyclic antidepressants	121 (22.3)
Immunosuppressants drugs	117 (21.5)
Narrowband UVB	10 (1.8)

Data are *n* (%) unless otherwise specified. BMI, body mass index; HBV, hepatitis C virus; HCV, hepatitis C virus; UVB, ultraviolet B.

Effectiveness outcomes

Treatment with dupilumab led to a rapid and sustained improvement in itch severity. The mean WI-NRS score decreased significantly from 8.69 (SD 1.41) at baseline to 3.78 (SD 2.63) at week 12, and further to 2.67 (SD 2.59) at week 24. Continued improvement was observed at later timepoints, with mean scores of 1.99 (SD 2.39) at week 52, 1.79 (SD 2.36) at week 76, and 1.72 (SD 2.44) at week 104 ($P < 0.001$ for trend) (Table 2).

Skin clearance, defined as the proportion of patients achieving an IGA PN-S score of 0 or 1, demonstrated a slower but steady improvement over time (Table 2). At week 12, 45.1% (245/543) of

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Table 2 Therapeutic response of patients with prurigo nodularis (PN) during dupilumab treatment over time[a]

Scale	Therapeutic response, mean (SD)						
	Week 0 (*N* = 543)	Week 12 (*N* = 543)	Week 24 (*N* = 519)	Week 52 (*N* = 417)	Week 76 (*N* = 353)	Week 104 (*N* = 297)	*P*-value
WI-NRS	8.69 (1.41)	3.78 (2.63)	2.67 (2.59)	1.99 (2.39)	1.79 (2.36)	1.72 (2.44)	<0.001
IGA PN-S	3.42 (1.62)	1.68 (1.06)	1.24 (0.96)	0.92 (0.96)	0.82 (0.96)	0.78 (0.98)	<0.001
Skin Pain-NRS	6.62 (2.41)	2.49 (2.53)	1.66 (2.28)	1.24 (2.03)	1.21 (2.16)	1.16 (2.13)	<0.001
Sleep-NRS	7.09 (2.55)	2.37 (2.75)	1.59 (2.39)	1.10 (2.09)	1.06 (2.09)	1.09 (2.12)	<0.001
DLQI	17.40 (6.94)	6.69 (6.22)	4.51 (5.75)	3.09 (5.02)	2.93 (4.99)	2.57 (4.89)	<0.001

DLQI, Dermatology Life Quality Index; IGA PN-S, Investigator Global Assessment for PN-Stage; NRS, numeric rating scale; WI-NRS, Worst Itch Numeric Rating Scale.
[a]*N* indicates the number of patients assessed at each visit using the last observation carried forward method. *P*-values were derived from the Friedman test for repeated measures to evaluate within-participant changes over time.

patients had already reached this threshold, and the proportion increased progressively with longer treatment exposure. By week 52, 77.0% (321/417) of patients had achieved IGA 0–1, a rate that remained stable thereafter, with comparable values observed at weeks 76 and 104 (Figure 1).

Other disease-related symptoms displayed a comparable time course, with skin pain decreasing from a mean baseline score of 6.62 (SD 2.41) to 2.49 (SD 2.53) at week 12 and subsequently remaining at low levels during follow-up visits. Sleep quality showed parallel improvements, with Sleep-NRS decreasing from 7.09 (SD 2.55) at baseline to 2.37 (SD 2.75) at week 12, and further to 1.09 (SD 2.12) at week 104.

Quality of life improved substantially as reflected by the DLQI, which fell from 17.40 (SD 6.94) at baseline to 6.69 (SD 6.22) at week 12, 4.51 (SD 5.75) at week 24, and continued to decrease to 2.57 (SD 4.89) at week 104 ($P < 0.001$). These findings were consistent with categorical analyses. As shown in Figure 1, the proportion of patients achieving at least a 4-point reduction in WI-NRS from baseline increased from 68.9% (374/543) at week 12 to 78.6% (408/519) at week 24, and peaked at 87.8% (310/353) by week 76, with 86.9% (258/297) maintaining this response at week 104. This indicates that the vast majority of patients not only improved but also sustained clinically meaningful itch relief throughout 2 years of treatment. Representative clinical images illustrate this evolution, showing improvement of nodular lesions and residual post-inflammatory changes after 24 weeks of therapy compared with baseline (Figure 2).

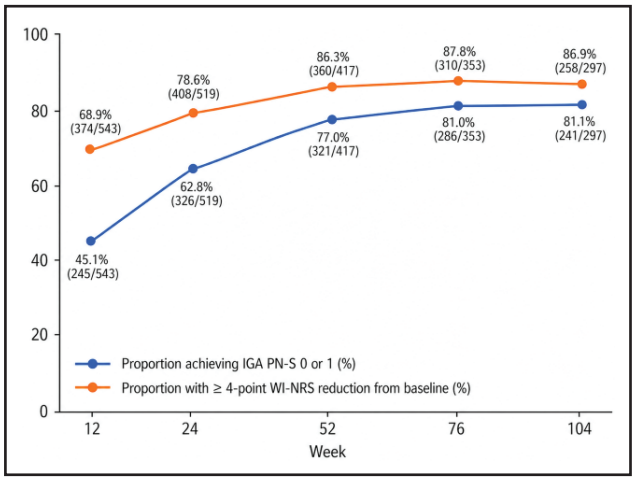

Figure 1 Proportion of patients achieving Investigator Global Assessment for PN-Stage (IGA PN-S) 0 or 1 and proportion of patients with ≥ 4-point Worst Itch Numeric Rating Scale (WI-NRS) reduction from baseline over time. Percentages are shown for each assessment timepoint.

Predictors of treatment response: univariate and multivariate analysis

Univariate logistic regression analyses identified several baseline variables significantly associated with clinical response, including reduction of ≥ 4 points in WI-NRS and achievement of IGA 0 or 1 (Tables S1 and S2; see Supporting Information). At 12 weeks, higher baseline WI-NRS scores, presence of cardiovascular disease and previous topical or systemic antihistamine therapies were positively associated with ≥ 4-point reduction in WI-NRS, whereas prior use of tricyclic antidepressants was negatively associated (odds ratio 0.15, 95% confidence interval 0.06–0.36, $P < 0.001$). Similar trends persisted at later timepoints, with a higher baseline WI-NRS consistently predicting greater reductions at 24, 52, 76 and 104 weeks.

A higher Sleep-NRS at baseline also emerged as a significant predictor at 52 and 76 weeks. For achievement of IGA 0 or 1, prior tricyclic antidepressant use and psychiatric comorbidities were consistently associated with a lower likelihood of response. Multivariate stepwise logistic regression analyses confirmed baseline WI-NRS as a strong independent predictor of ≥ 4-point reduction at all evaluated timepoints, together with cardiac comorbidities at 12–24 weeks, BMI at 24 weeks and prior corticosteroid therapies at 76 weeks (Table S3; see Supporting Information). Regarding IGA 0 or 1, baseline DLQI, prior tricyclic antidepressant use and psychiatric comorbidities remained significant negative predictors, particularly at early (12–24 weeks) and mid-term follow-up. Overall, these analyses highlight baseline disease severity, comorbidities and treatment history as key determinants of clinical response over time. Notably, neither the concomitant presence nor a history of atopic dermatitis had any impact on the likelihood of achieving a ≥ 4-point reduction in WI-NRS or attaining IGA 0/1.

Laboratory outcomes

Longitudinal evaluation of laboratory parameters demonstrated a progressive and statistically significant decline in total IgE

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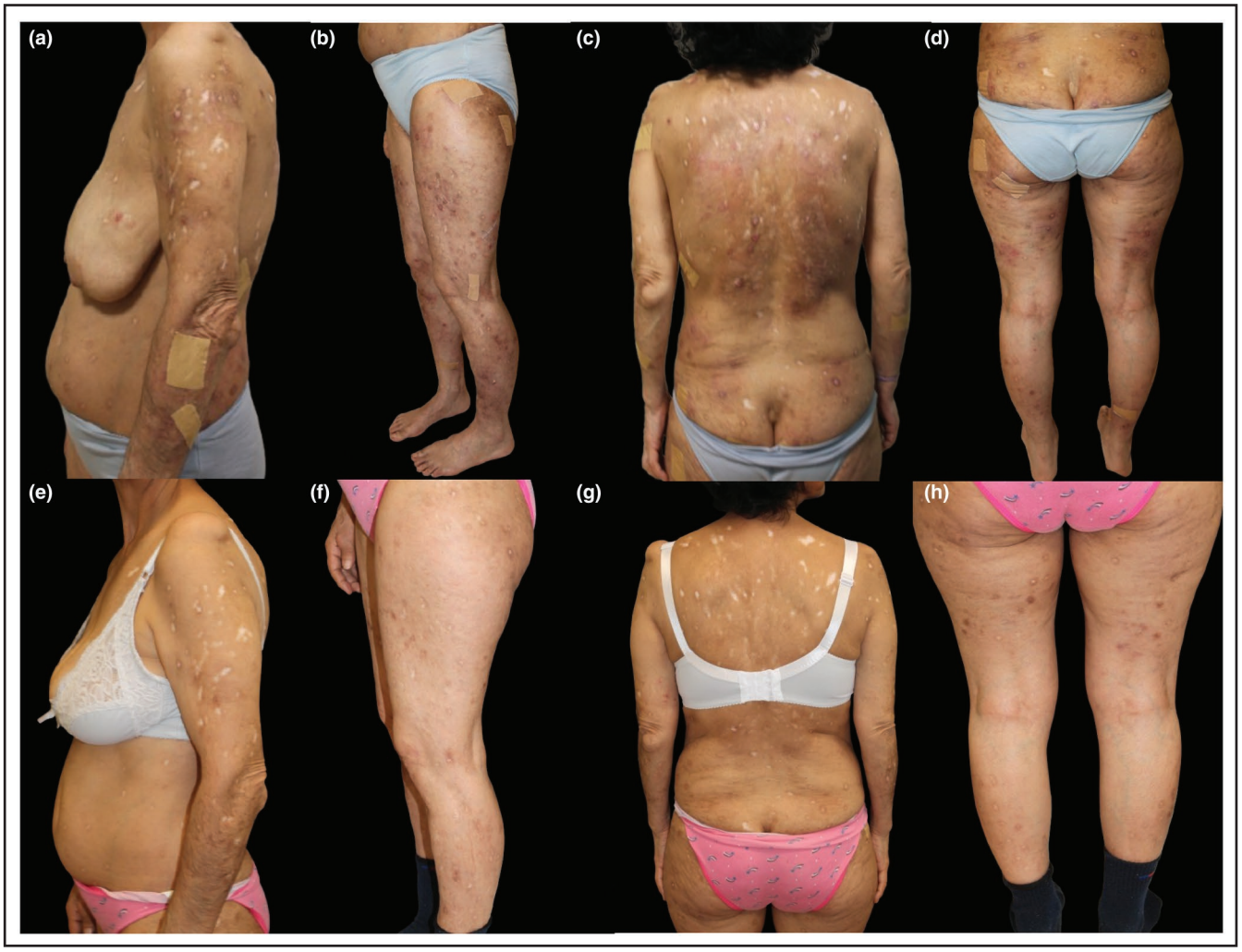

Figure 2 Clinical images of a patient with prurigo nodularis (PN) before and after treatment with dupilumab. (a–d) Baseline: before initiation of dupilumab therapy, showing widespread nodular lesions on the trunk and extremities [Worst Itch Numeric Rating Scale (WI-NRS): 10; Investigator Global Assessment for PN-Stage (IGA PN): 4]. (e–h) After 24 weeks of treatment: marked improvement with mainly postinflammatory changes and residual scars visible (WI-NRS: 3; IGA PN: 1). This patient's case was intentionally selected because it represents an emblematic and clinically meaningful presentation of PN. The patient had applied adhesive patches over nodules to avoid scratching, demonstrating mechanical suppression of scratching and interruption of the itch–scratch cycle, central to PN pathophysiology. Additionally, she developed lesions on the mid-back by using external objects to reach otherwise inaccessible areas, highlighting the behavioural and neurosensory components of PN. This patient's case provides a didactic visual example of disease mechanisms beyond classical distribution patterns.

Table 3 Longitudinal changes in laboratory indices in patients with prurigo nodularis during dupilumab treatment[a]

	Therapeutic response, mean (SD)					
Indices	**Week 0 (*N* = 268)**	**Week 24 (*N* = 105)**	**Week 52 (*N* = 72)**	**Week 76 (*N* = 44)**	**Week 104 (*N* = 38)**	***P*-value**
Total IgE (kU L^{-1})	989 (1817)	502 (1087)	277 (569)	264 (564)	155 (186)	<0.001
Eosinophil count ($\times 10^9$ L^{-1})	0.47 (0.49)	0.29 (0.27)	0.41 (0.91)	0.26 (0.22)	0.36 (0.51)	0.01
LDH (U L^{-1})	211 (81.5)	189 (46.4)	202 (43.7)	211 (55.5)	201 (63.2)	0.53

LDH, lactate dehydrogenase. [a]*N* indicates the number of patients for whom each laboratory index was available at each visit, assessed using the last observation carried forward method. *P*-values were derived from the Friedman test for repeated measures to evaluate changes in total IgE, eosinophil count and LDH over time.

concentrations over the course of dupilumab treatment (Table 3). Mean IgE values decreased from 989 (SD 1817) kU L^{-1} at baseline to 502 (SD 1087) kU L^{-1} at week 24, 277 (SD 569) kU L^{-1} at week 52 and further to 155 (SD 186) kU L^{-1} at week 104 ($P < 0.001$). Eosinophil counts showed modest fluctuations over time, with a baseline mean of 0.47 (SD 0.49) $\times 10^9$ L^{-1}, a reduction to 0.29 (SD 0.27) $\times 10^9$ L^{-1}, at week 24, and variable values at later assessments [0.41 (SD 0.91) $\times 10^9$ L^{-1}, at week 52, 0.26 (SD 0.22) $\times 10^9$ L^{-1}

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at week 76 and 0.36 (SD 0.51) $\times 10^9$ L^{-1}, at week 104] ($P = 0.01$). In contrast, lactate dehydrogenase (LDH) levels remained stable throughout follow-up, with no significant differences compared with baseline [mean 211 (SD 81.5) U L^{-1} at baseline vs. 201 (SD 63.2) U L^{-1} at week 104] ($P = 0.53$).

Correlation analyses at baseline showed that total IgE levels were only weakly associated with disease severity (Table S4; see Supporting Information). A modest but statistically significant positive correlation was observed between total IgE and IGA PN-S scores ($\rho = 0.181$, $P = 0.01$), whereas no significant associations were detected with WI-NRS, skin pain, sleep disturbance or DLQI. Conversely, strong correlations were evident among the clinical measures themselves. WI-NRS was significantly associated with IGA PN-S ($\rho = 0.262$, $P < 0.001$), skin pain ($\rho = 0.375$, $P < 0.001$), sleep disturbance ($\rho = 0.515$, $P < 0.001$) and DLQI ($\rho = 0.247$, $P < 0.001$). Similarly, sleep disturbance showed strong correlations with both skin pain ($\rho = 0.600$, $P < 0.001$) and a weak correlation with DLQI ($\rho = 0.344$, $P < 0.001$).

Adverse events and dropout from treatment

Among the 543 patients included in the study, the overall treatment discontinuation rate was 19.7% ($n = 107$). The most common reason was loss to follow-up (9.8%, $n = 53$), while a small proportion (0.7%, $n = 4$) discontinued therapy by personal choice. Lack of efficacy, defined as insufficient control of pruritus or persistence of nodular lesions, accounted for 6.3% of discontinuations ($n = 34$). Adverse events led to treatment interruption in 2.9% of patients ($n = 16$), most frequently because of conjunctivitis ($n = 6$), followed by psoriasis exacerbation ($n = 2$), arthralgia ($n = 2$) and one participant each because of myalgia, lymphadenopathy, fever, gingival erosions, anaemia and photodermatitis.

Additional adverse events not requiring discontinuation included arthralgia ($n = 3$ further cases in participants), conjunctivitis ($n = 6$), rosacea eruption ($n = 3$), telogen effluvium ($n = 2$), psoriasis ($n = 2$), and isolated cases of dyslipidaemia, oral candidiasis, oral ulcers, diarrhoea and facial erythema. Importantly, no cases of malignancy progression or reactivation of chronic viral infections [hepatitis C virus (HCV), hepatitis B virus (HBV) or HIV] were observed during dupilumab therapy in the participants.

Discussion

This multicentre, real-world systematic data collection offers long-term insights into the effectiveness and safety of dupilumab in PN, including patients with systemic comorbidities. To our knowledge, this is one of the largest cohorts reported to date, with over 500 patients followed for up to 104 weeks. Overall, our results reinforce and extend the evidence from pivotal randomized trials and previous real-world series demonstrating that dupilumab delivers durable benefits across key disease domains – including itch, skin clearance, sleep, pain and quality of life. In our real-world cohort, response rates were not only comparable but in fact higher, with 78.6% (408/519) of patients achieving a $\geq$4-point WI-NRS reduction by week 24, compared with 60% in PRIME. Moreover, long-term follow-up up to 2 years showed that clinical responses deepened and were maintained, highlighting the durability of dupilumab's effect beyond the timeframe of the phase III trials. Our study also included patients with multiple comorbidities, who are typically excluded from clinical trials, and both effectiveness and safety outcomes remained favourable, further supporting the utility of dupilumab in routine clinical practice.

Our results are also consistent with previously published real-life studies.[17,23] A more recent Chinese multicentre study with 73 patients demonstrated that by week 12, nearly 85% achieved PP-NRS4 and 37–47% reached IGA 0/1 at weeks 12–16, with parallel gains in quality of life.[16] These early improvements are consistent with the rapid antipruritic effects observed in our cohort, although our long-term data demonstrate further progressive benefits up to 2 years. Taken together, these real-world studies, together with our large multicentre experience, reinforce the external validity of clinical trial results and highlight dupilumab's sustained effectiveness and safety in diverse PN populations.

From a laboratory perspective, dupilumab induced a progressive and significant decline in total IgE levels over 2 years, consistent with its mechanism of action on the IL-4/IL-13 signalling pathway. However, correlations between IgE and disease severity were weak in our cohort, underscoring that IgE cannot be used as a reliable biomarker for PN severity or treatment response. Interestingly, our results contrast with a recent retrospective study suggesting that elevated baseline IgE levels predicted greater relief from pruritus with dupilumab, raising the possibility of IgE as a biomarker for treatment stratification.[24] These discrepancies highlight the need for further prospective studies to clarify whether IgE truly has predictive value in PN or whether other inflammatory markers may provide more reliable guidance. Eosinophil counts fluctuated modestly, without clear clinical significance, and LDH levels remained stable. Taken together, these findings suggest that, similar to atopic dermatitis, clinical parameters remain superior to serological markers for monitoring treatment outcomes in PN.

A strength of our study is the exploration of potential predictors of treatment response. Logistic regression analyses revealed that baseline disease severity, as reflected by a higher baseline WI-NRS score, was the most consistent and independent predictor of clinically meaningful pruritus reduction across all timepoints, confirming that patients with higher symptom burden are most likely to benefit from dupilumab. Interestingly, cardiovascular comorbidities were also associated with better outcomes at earlier timepoints, although the biological plausibility of these associations remains unclear and may be confounded by demographic or clinical factors. An interesting finding of our regression analyses was the consistent identification of previous tricyclic antidepressant use and psychiatric comorbidities as negative predictors of dupilumab response. Rather than suggesting misdiagnosis in these patients, this observation may reflect the complex bidirectional interplay between psychogenic pruritus and PN, as PN can also arise as a complication of chronic pruritus with a psychiatric component. In such patients, a combined therapeutic strategy, including both dupilumab and antidepressant therapy, may be particularly relevant. Moreover, our results indicate that dupilumab can still be effective in patients with other pruritogenic comorbidities, which deserves emphasis.

These findings raise an important practical question regarding timing and extent of aetiological workup. Although a comprehensive assessment remains desirable, it may be most clinically useful to prioritize it in patients where there is suboptimal or absent response to dupilumab. Overall, our data support a nuanced,

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multidisciplinary approach that integrates dermatological and psychiatric perspectives while avoiding premature exclusion of patients from biologic therapy.

Baseline DLQI also emerged as a negative predictor for achieving IGA 0/1, reinforcing the interplay between quality of life impairment and therapeutic response. These findings align with previous observations in other inflammatory dermatoses,[25] where baseline severity and comorbidity burden modulate response to biologic therapy. Overall, our results emphasize the importance of comprehensive baseline assessment, including clinical history and psychiatric evaluation, to better stratify patients and optimize treatment strategies in PN. Safety analysis confirmed the favourable tolerability of dupilumab. The discontinuation rate because of adverse events was low (2.9%), and most adverse events were mild or manageable, consistent with the known safety profile of dupilumab in other type 2 inflammatory diseases.[26] Conjunctivitis was the most frequently reported event, but severe ocular complications were not observed.[27] Importantly, no reactivation of chronic infections (HBV, HCV, HIV) occurred, and no progression or recurrence of malignancy was detected in patients with prior cancer, providing reassuring data for clinicians managing patients with these comorbidities.[28,29] Clinically relevant, dupilumab was also well tolerated in patients with chronic kidney disease, without signs of renal function deterioration or treatment-related complications, in keeping with previous real-world reports supporting its safety in this fragile population.[30] These findings are highly relevant given the high prevalence of systemic diseases in patients with PN, which often complicates systemic treatment decisions and limits the use of immunosuppressants or corticosteroids. Dupilumab's targeted mechanism of action and absence of broad immunosuppression probably explain this favourable profile.

Our results also highlight the importance of long-term follow-up in PN. Whereas short-term studies demonstrated early effectiveness, our 2-year data indicate that responses are not only durable but also continue to deepen over time, particularly with respect to nodule clearance and quality of life restoration. This has significant implications for clinical practice: patients and physicians should be aware that maximal benefits may require sustained treatment, and premature discontinuation could undermine outcomes. Moreover, the relatively low dropout rate because of inefficacy (6.3%) suggests that most patients can expect meaningful and lasting benefits.

The strengths of our experience include the large sample size, extended follow-up and the inclusion of patients with a broad spectrum of comorbidities, offering a reliable reflection of routine clinical practice. However, some limitations should be acknowledged. The retrospective design and intercentre variability may introduce biases, and data from the first 12 weeks of treatment were not captured. In addition, laboratory data at week 12 were not systematically collected. The inclusion of patients with ≥ 20 nodules, WI-NRS ≥ 7, and at least 12 weeks of dupilumab monotherapy probably selected patients with more severe cases, limiting generalizability and potentially affecting outcomes. Moreover, the exclusion of patients with end-stage chronic kidney disease, severe hepatic impairment or uncontrolled diabetes may further limit the applicability of these findings to the overall PN population.

The fluctuating course of PN may overestimate long-term benefits, the absence of a control group prevents causal inference, and analyses of biomarkers such as IgE and eosinophils should be interpreted cautiously because of small sample sizes. Finally, although potential predictors of response emerged, these require confirmation in prospective, controlled settings to establish their value for guiding personalized treatment strategies.

In conclusion, dupilumab provides durable improvements in pruritus, lesion clearance, sleep, pain and quality of life in people with PN, with a favourable safety profile even in patients with comorbidities. These findings support the growing role of dupilumab as a key systemic treatment option for moderate-to-severe disease. Future research is warranted to identify biomarkers of response, explain reduced effectiveness in patients with psychiatric comorbidities, and evaluate the long-term impact of dupilumab on disease and healthcare burden.

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Conflicts of interest

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Data availability

The data underlying this article will be shared upon reasonable request to the corresponding author.

Ethics statement

This work was based on the systematic and continuous collection of clinical data within routine practice across Italian dermatology centres. According to current Agenzia Italiana del Farmaco guidance, registry-based data collection without predefined study endpoints is not classified as an observational study; therefore, ethics committee approval and individual informed consent were not required, except for the publication of patients' clinical photographs. All data were handled in compliance with applicable privacy regulations and anonymized prior to analysis.

Patient consent

The patient provided written informed consent for the publication of her clinical photographs and anonymized clinical data.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website.

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