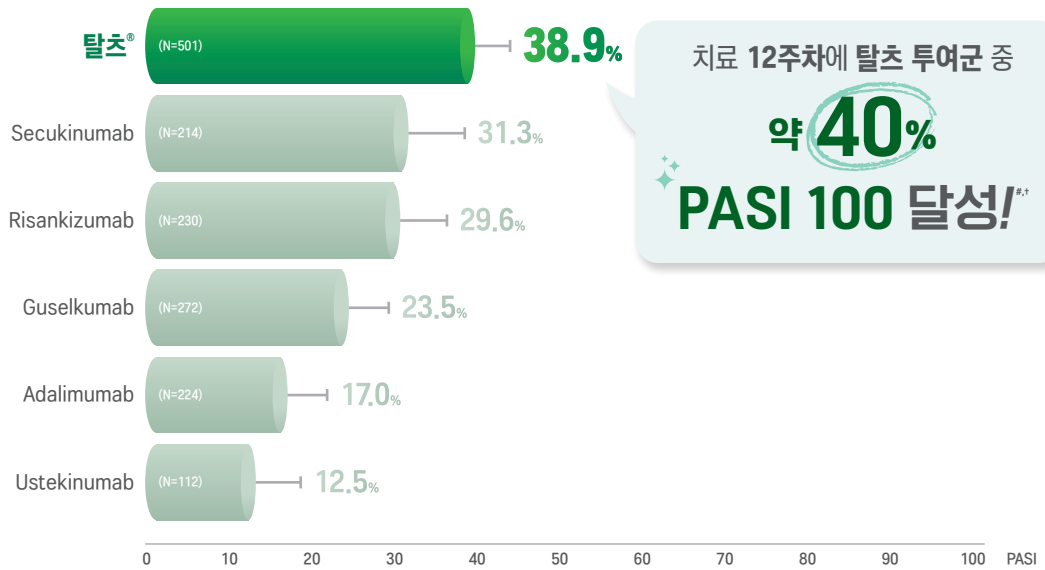
탈츠®의 빠른 피부개선 효과가 실제 진료 환경에서도 확인되었습니다![1]

New real-world data from PSoHO

Percentage of patients[§] who achieved PASI 100 at Week 12 (upper 95% CI)



치료 12주차에 탈츠 투여군 중

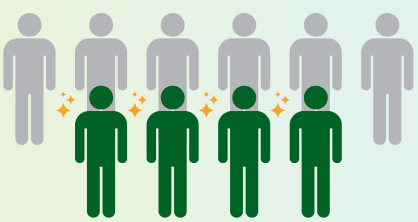
약 40%

PASI 100 달성![#,†]

탈츠® 투여군에서

10명 중 약 4명의 환자가

12주 만에 PASI 100 달성[#,†]



taltz® (ixekizumab)

PASI : Psoriasis Area and Severity Index

실제 진료 환경에서도 효과가 확인된 탈츠®로 건선 치료를 시작해주세요![1,2]

All

탈츠®는 기존 생물학적제제 **치료 유무와 상관없이 모두**에게 **유의하게 높은 효과를** 보였습니다.[5]

1

탈츠®는 **1주** 만에 건선 환자에게 유의하게 **높은 병변 개선**을 보였습니다.[3,6]

100

탈츠® 치료 12주째 환자 중 **40%가 PASI 100에 도달**하였습니다.[3,4]

264

탈츠® 치료 12주째 달성한 **PASI 개선율**은 치료 **264주차**에 **걸쳐 지속**되었습니다.[7]

탈츠®는 PASI 90 / PASI 100 도달을 통해 삶의 질을 더욱 유의하게 개선시켰습니다.[3]

효능/효과[2,*]

- **중등도에서 중증의 판상 건선**
- **건선성 관절염**
- **강직성 척추염**
- **비-방사선성 축방향 척추관절염**

* 1) 판상 건선 : 광선 요법 또는 전신치료요법을 필요로 하는 중등도에서 중증의 판상 건선의 치료 2) 건선성 관절염 : 이전에 DMARDs(disease-modifying anti-rheumatic drug)에 대한 반응이 적절하지 않거나, 내약성이 없는 활동성 건선성 관절염의 치료 3) 강직성 척추염 : 기존 치료에 대한 반응이 적절하지 않은 활동성 강직성 척추염의 치료 4) 비-방사선성 축방향 척추관절염 : 비스테로이드성 항염증 약물(NSAIDs)에 대한 반응이 적절하지 않고 상승된 CRP 수치 및/또는 MRI상 객관적인 염증의 징후를 보이는 활동성 비-방사선성 축방향 척추관절염 환자의 치료'
'patients who received the EMA approved on-label dosing

* Data presented from subgroup of patients who received the EMA approved on-label dosing; unadjusted CIs were calculated using the normal approximation; for missing data, the outcomes of interest were imputed using NRI. † Unadjusted, actual response rates of PASI100 responses at Week 12 for the individual drugs; FMA ORs (95% CIs) for PASI100 were reported as 1.5 (1.1, 2.2) for Taltz vs. secukinumab, 1.6 (1.2, 2.2) for Taltz vs. risankizumab, 2.1 (1.5, 2.7) for Taltz vs. guselkumab, 3.8 (2.5, 5.9) for Taltz vs. adalimumab, and 4.8 (2.7, 9.1) for Taltz vs. ustekinumab; FMA results are not shown here.'

PSoHO(N=1981) The Psoriasis Study of Health Outcomes (PSoHO) is an ongoing 36-month prospective, multicentre, international, non-interventional cohort study reflecting treatment with biologics within real-world settings. This study has been designed to compare the effectiveness of anti-interleukin (IL)-17A biologics relative to other approved biologics in patients with moderate-to-severe psoriasis(PsO). Eligible patients were 1981 adults (age ≥18) with an established diagnosis (at least 6 months prior to baseline) of moderate-to-severe PsO. Biologics used in this study are the anti-IL-17A antibodies (ixekizumab [IXE](n=532) and secukinumab [SEC](n=241)) and any other biologics(n=1,208) indicated for the treatment of moderate-to-severe PsO. The primary endpoint is the proportion of patients achieving 90% improvement in Psoriasis Area and Severity Index (PASI 90) and/or static Physician Global Assessment (sPGA) 0/1 at Week 12 in the anti-IL-17A cohort (IXE and SEC) vs. all other approved biologics.

UNCOVER-1 (N=1,296), UNCOVER-2 (N=1,224), and UNCOVER-3 (N=1,346) The studies were phase 3, multicenter, randomized, double-blind, placebo-controlled trials to evaluate the efficacy and safety of Taltz. All patients were ≥18 years of age, had plaque psoriasis with a body surface area involvement of ≥10%, had a static Physician's Global Assessment (sPGA) score ≥3 and Psoriasis Area and Severity Index (PASI) score ≥12, and were candidates for phototherapy and/or systemic therapy. In all 3 trials during the induction period, participants were randomized to receive placebo or Taltz 80 mg every 2 or 4 weeks following a 160-mg starting dose. In UNCOVER-2 and UNCOVER-3, an additional arm of etanercept (50 mg twice weekly) was included. Co-primary efficacy endpoints were the proportion of patients achieving sPGA 0 or 1 and proportion of patients achieving PASI 75 at week 12. Additional prespecified secondary endpoints included an assessment of health-related quality of life using the Dermatology Life Quality Index (DLQI) and patient-reported itch severity over 24 hours using the Itch Numeric Rating Scale (I-NRS), where scores range from 0 ("no itch") to 10 ("worst itch imaginable"). For categorical values, all missing data were imputed using the NonResponder Imputation (NRI), in which all patients with missing data at a given visit were considered nonresponders. Patients originally randomized to Taltz who had an sPGA 0,1 response at week 12 in UNCOVER-1 and UNCOVER-2 were re-randomized to either Taltz 80 mg every 4 or 12 weeks or placebo for a 48-week maintenance period. Patients who relapsed (sPGA ≥3) received open-label Taltz 80 mg every 4 weeks. In UNCOVER-3, all patients entered a long-term extension at week 12 and received open-label Taltz 80 mg every 4 weeks.[11]

Long term extension of UNCOVER-3 (N=385) This trial was a long term extension (LTE) analysis of the UNCOVER-3 study which is a randomized, double-blind, multicenter, phase 3 study in patients with moderate to severe plaque psoriasis. This study was conducted to report efficacy and safety over 5 years (264 weeks) of treatment with the approved IXE dose from the UNCOVER-3 study. Among 1,346 patients, 385 patients were randomly assigned Q2W or Q4W groups after receiving IXE 80 mg Q2W up to 12 wk (Q2W group : IXE 80 mg Q4W up to week 60 + IXE 80 mg Q2W thereafter; Q4W group : IXE 80 mg Q4W until end of study). Efficacy data were summarized at each post-baseline visit through 264 weeks by using 3 methods: as observed, multiple imputation (MI), and modified nonresponder imputation (mNRI). The efficacy endpoints at week 264 included percentage of patients who achieved at least 75%, 90%, or 100% improvement from baseline in the PASI (75/90/100, respectively) and the percentage of patients who achieved a sPGA score of 1 (minimal) or 0 (clear).'

References **1.** Pinter A, *et al. J Eur Acad Dermatol Venereol.* 2022;36:2087-2100. **2.** 탈츠 식약처 허가사항(의약품안전나라의약품통합정보시스템(https://nedrug.mfds.go.kr))[revised on 29 Nov 2021]. **3.** Griffiths CE, Reich K, Lebwohl M, *et al*; for the UNCOVER-2 and UNCOVER-3 Investigators. Comparison of ixekizumab with etanercept or placebo in moderate-to-severe psoriasis (UNCOVER-2 and UNCOVER-3): results from two phase 3 randomised trials. *Lancet*. 2015;386:541-551. **4.** Taltz [summary of product characteristics]. Utrecht, The Netherlands: Eli Lilly Nederland B.V.; 2020. **5.** Gottlieb AB *et al.* Treatment outcomes with ixekizumab in patients with moderate-to-severe psoriasis who have or have not received prior biological therapies: an integrated analysis of two Phase III randomized studies. *J Eur Acad Dermal Venereol* 2017 Apr;31(4):679-685. **6.** Leonardi C, *et al. JAAD* 2016 74(5)(suppl):AB70. **7.** Andrew Blauvelt, *et al*. Long-term efficacy and safety of ixekizumab: A 5-year analysis of the UNCOVER-3 randomized controlled trial. *J Am Acad Dermatol*. 2021 Aug;85(2):360-368.

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