

Media Backgrounder

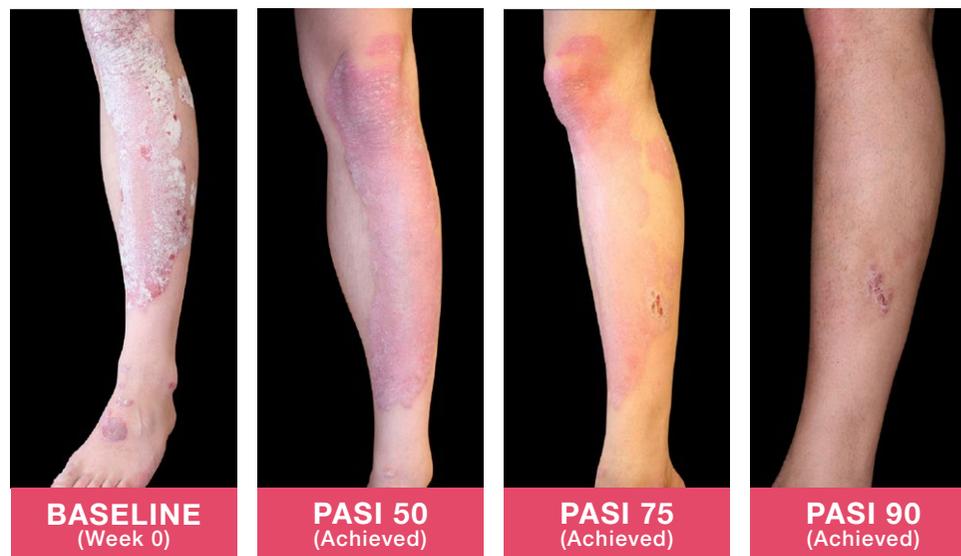
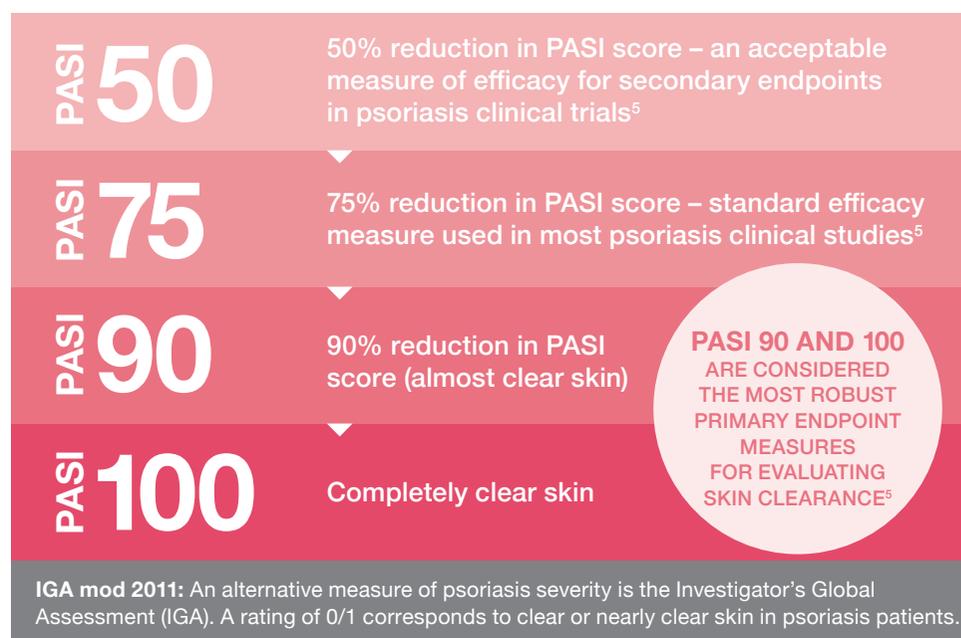
PASI Scores Measuring Skin Clearance for Psoriasis Patients in Clinical Trials

Why is it important that therapies for psoriasis achieve clear skin?

Psoriasis is a chronic immune-mediated disease characterized by thick and long lasting skin lesions, called plaques, known to cause itching, scaling and pain¹⁻³. This common and distressing condition is not simply a cosmetic problem – even people with very mild symptoms are affected everyday¹. Psoriasis is associated with significant impairment of physical and psychological quality of life. People living with the condition are also more likely suffer from a range of conditions that may occur simultaneously such as psoriatic arthritis, heart disease and cancer (lymphoma)¹⁻³. Consequently there is an urgent need for new treatments that **achieve clear or almost clear skin**, as a proven link exists between this and health-related quality of life¹⁻⁴.

Measuring psoriasis skin clearance in clinical trials

The Psoriasis Area and Severity Index (PASI) is frequently used to measure outcomes in psoriasis clinical trials and measures the redness, scaling and thickness of psoriatic plaques and the extent of involvement in each region of the body⁵. During clinical trials, psoriasis treatment efficacy is assessed by the reduction of the score from baseline (week 0)⁵.



Clear skin is the desired outcome for most psoriasis patients¹⁻⁴, establishing a more accurate primary endpoint is critical

Historically, achieving PASI 75 has been the goal for psoriasis treatments, and as a consequence this measure has been regularly used as the primary endpoint in clinical trials⁵. However, there is now a continued focus on the establishment of PASI 90 and PASI 100 as the preferred efficacy measure, as recommended by clinical guidelines and regulatory authorities⁵. This is because these measures accurately reflect the patient's treatment goals, as well as ensuring thorough evaluation of patient progress throughout clinical trials⁵.

REFERENCES

1. Stern RS, Nijsten T, Feldman S, et al. "Psoriasis Is Common, Carries a Substantial Burden Even When Not Extensive, and Is Associated with Widespread Treatment Dissatisfaction." *J Investig Dermatol Symp.* 2004;9(2):136-9.
2. Rapp SR, Feldman SR, Exum ML, Fleischer AB, Jr., Reboussin DM. "Psoriasis causes as much disability as other major medical diseases." *J Am Acad Dermatol.* 1999; 41(3 Pt 1):401-7.
3. Farley E et al. "Psoriasis: comorbidities and associations." *G Ital Dermatol Venereol.* 2011 Feb;146(1):9-15.
4. McLeod LD, Mallya UG, Fox T, Strober BE. "Psoriasis Patients With PASI 90 Response Achieve Greater Health-Related Quality-of-Life Improvements Than Those With PASI 75 Response." *European Association of Dermatology and Venereology Congress.* Amsterdam, Netherlands. 10 October 2014.
5. Guideline on clinical investigation of medicinal products indicated for the treatment of psoriasis. European Medicines Agency Web site. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003329.pdf Published November 2004. Accessed January 2015.

PATIENT PROGRESS WITH TREATMENT OVER THE COURSE OF 36 WEEKS

BASELINE

Patient assessment begins at baseline (week 0).



PASI 90

PASI 90 or almost clear skin, was achieved between week 0 and week 24.



PASI 100

PASI 100 or clear skin, can be seen at week 36.

