Tremfya® (guselkumab)

Demonstrated sustained relief in Psoriasis at 5 years and in Psoriatic Arthritis at 2 years*[1,2]

COMPLETE SKIN CLEARANCE

- **At Week 16:** PASI 100 achieved in more than 1/3 of PsO patients treated with TREMFYA®.[†3]
- **Long term:** PASI 100 response rate of over 50% at Week 52 sustained at 5 years in PsO patients treated with TREMFYA®.[†1]

RAPID JOINT EFFICACY

- **At Week 4:** ACR20 achieved in 20% of PsA patients treated with TREMFYA®.[2]
- **Long term:** 74% ACR20 response rate seen at 1 year and sustained at 2 years in PsA patients treated with TREMFYA®.[¶2,4]

PROVEN DURABILITY

- Most patients who started on TREMFYA®, stayed on TREMFYA® long-term.[2,5]

To access educational videos, clinical papers, patient support and more visit **https://www.janssenmedicalcloud.co.uk/** or scan the QR code.

*Sustained improvements in psoriasis disease severity (as measured by PASI 90 and PASI 100 scores) and sustained improvements in psoriatic arthritis disease severity (as measured by ACR scores, HAQ-DI scores and resolution of enthesitis and dactylitis).[1,2] †PASI 100 analysis not part of the statistical analysis plan. 37.4% of patients treated with TREMFYA® achieved PASI 100 at Week 16 (n=329) vs 0.6% of patients treated with placebo (n=174; p<0.001; Non-responder imputation [NRI]).[3] ‡Patients achieving PASI 100 at Week 52: 50.5% (Treatment failure rules [TFR]), 51.3% (As observed), and 47.1% (NRI). In patients randomised to TREMFYA® at baseline. Patients achieving PASI 100 at Week 252: 51% (TFR), 52.8% (As observed) and 39.5% (NRI).[1] ¶In patients treated with TREMFYA® q8w. 74.6% (n=248) of TREMFYA® q8w patients achieved ACR20 at 1 year, and 74% (n=248) of TREMFYA® q8w patients achieved ACR20 at 2 years (NRI).[2,4] Complete skin clearance: Psoriasis Area and Severity Index [PASI] 100.[6] ACR20 – 20% improvement in a set of core measures: tender joint count, swollen joint count, patient's assessment of pain, patient's global assessment of disease activity, physician's assessment of physical function, patient's assessment of physical function and acute-phase reactant value.[7] Durability, also known as patient retention or drug survival, is a combination of efficacy, safety, tolerability and patient satisfaction or preference.[8] VOYAGE 1 was a Phase 3, double-blind, placebo- and active comparator-controlled clinical trial that evaluated the efficacy and safety of TREMFYA® in patients with moderate-to-severe plaque psoriasis.[1] DISCOVER-2 was a Phase 3, double-blind, multi-centre, placebo-controlled clinical trial that evaluated the efficacy and safety of TREMFYA® in bio-naïve patients with active PsA.[9] TREMFYA® is indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy.[10] TREMFYA®, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.[10]

References: 1. Griffiths CEM, et al. Maintenance of Response Through 5 Years of Continuous Guselkumab Treatment: Results From the Phase 3 VOYAGE 1 Trial. Presented at the 16th Annual Coastal Dermatology Symposium. October 15-16, 2020. **2.** McInnes IB, et al. Arthritis Rheumatol. 2021 Nov 1. doi: 10.1002/art.42010. **3.** Blauvelt A, et al. J Am Acad Dermatol 2017;76:405-417. **4.** McInnes IB, et al. Arthritis Rheumatol. 2021;73:604-616. **5.** Blauvelt A, et al. J Am Acad Dermatol 2021;S0190-9622:02816-4. **6.** Strober B, et al. J Am Acad Dermatol 2016;75:77-82.e7. **7.** Felson DT, LaValley MP. Arthritis Res Ther 2014;16:101. **8.** Geale K, et al. Rheumatol Adv Pract 2020;4:rkaa070. **9.** Mease PJ, et al. Lancet 2020;395:1126-1136 (Including supplementary appendix). **10.** TREMFYA® (guselkumab) 100 mg Summary of Product Characteristics.

ACR, American College of Rheumatology; **HAQ-DI**, Health Assessment Questionnaire - Disability Index; **PASI**, Psoriasis Area and Severity Index; **PsA**, psoriatic arthritis; **PsO**, psoriasis; **q8w**, every 8 weeks.

Tremfya▼ 100 mg solution for injection in pre-filled pen
PRESCRIBING INFORMATION
ACTIVE INGREDIENT(S): Guselkumab
Please refer to Summary of Product Characteristics (SmPC) before prescribing. **INDICATION(S):** Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Treatment of active psoriatic arthritis in adult patients, alone or in combination with methotrexate, who have had an inadequate response or have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. **DOSAGE & ADMINISTRATION:** For use under guidance/supervision of physician experienced in diagnosis and treatment of conditions for which Tremfya is indicated. Subcutaneous injection. Avoid areas showing psoriasis. **Adults:** For both indications, 100 mg at weeks 0 and 4, followed by maintenance dose every 8 weeks. In the case of psoriatic arthritis, for patients at high risk for joint damage according to clinical judgement, consider a dose of 100 mg every 4 weeks. Consider discontinuation if no response after 16 weeks of treatment for plaque psoriasis and after 24 weeks for psoriatic arthritis. **Children:** No data available in children/adolescents <18 years. **Elderly:** No dose adjustment required, limited information in subjects aged ≥ 65 years, very limited information > 75 years. **Renal & Hepatic impairment:** Not studied. **CONTRAINDICATIONS:** Serious hypersensitivity to active substance or excipients; clinically important, active infection. **Refer to SmPC for full list of excipients. SPECIAL WARNINGS & PRECAUTIONS:** ***Infections:*** Potential to increase risk. If signs/symptoms of clinically important chronic/acute infection occur, monitor closely and discontinue Tremfya until resolved. ***Tuberculosis:*** Evaluate patients for TB pre-treatment; monitor for signs/symptoms of active TB during and after treatment. Consider anti-TB therapy prior to Tremfya if past history of latent/active TB and adequate treatment course not confirmed. ***Serious hypersensitivity reaction:*** Includes anaphylaxis. Some serious hypersensitivity reactions occurred several days after treatment and included urticaria and dyspnoea. If occurs, discontinue Tremfya immediately and initiate appropriate therapy. ***Hepatic Transaminase Elevations:*** An increased incidence of liver enzyme elevations has been observed in patients treated with Tremfya q4w compared to patients treated with Tremfya q8w or placebo. When prescribing Tremfya q4w in psoriatic arthritis, consider evaluating liver enzymes at baseline and thereafter according to routine patient management. If increases in ALT or AST are observed and drug-induced liver injury is suspected, Tremfya should be temporarily interrupted until this diagnosis is excluded. ***Immunisations:*** Consider completing all appropriate immunisations prior to Tremfya. Do not use live vaccines concurrently with Tremfya; no data available; before live vaccination, withhold Tremfya for at least 12 weeks and resume at least 2 weeks after vaccination. **SIDE EFFECTS: Very common:** Respiratory tract infection. **Common:** headache, diarrhoea, arthralgia, injection site reactions, transaminases increased. **Other side effects:** hypersensitivity, anaphylaxis, rash, gastroenteritis, herpes simplex infections, tinea infections, neutrophil count decreased, urticaria. **Refer to SmPC for more detail on side effects. PREGNANCY:** Avoid use of Tremfya; no data. Women of childbearing potential should use effective contraception during and for at least 12 weeks after treatment. **LACTATION:** It is unknown whether guselkumab is excreted in human milk. A decision should be made to discontinue, or abstain from initiating treatment with Tremfya taking into account the benefit of breast-feeding to the child and the benefit of Tremfya therapy to the woman. **INTERACTIONS:** No dose adjustment when co-administering with CYP450 substrates. Concomitant immunosuppressive therapy or phototherapy not evaluated. **Refer to SmPC for full details of interactions. LEGAL CATEGORY:** Prescription Only Medicine (POM) **PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S) & BASIC NHS COSTS**

PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBER(S)	BASIC NHS COSTS
Pre-filled pen (100mg)	X 1	NI: EU/1/17/1234/002 GB: PLGB 00242/0665	£2250

MARKETING AUTHORISATION HOLDER: Northern Ireland: Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium. Great Britain: Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK **FURTHER INFORMATION IS AVAILABLE FROM:** Janssen-Cilag Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK. Prescribing information last revised: June 2021

Adverse events should be reported. ▼This medicinal product is subject to additional monitoring and it is therefore important to report any suspected adverse events related to this medicinal product. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Janssen-Cilag Limited on 01494 567447 or at dsafety@its.jnj.com.

janssen Immunology
PHARMACEUTICAL COMPANIES OF Johnson&Johnson

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Counting dermatologists in South Africa: number, distribution and requirement

Dear Editor,

Dermatological diseases continue to contribute significantly to the burden of disease (BoD) worldwide, affecting all populations and age groups. Skin disease has been considered the fourth leading cause of non-fatal disease burden globally [1]. Low-socioeconomic settings reflect a high prevalence of dermatological disease ranging from 50-80% of the population [2]. Despite this high BoD in low- and middle-income countries, a shortage of dermatologists exists for most African countries (Namibia-0.8, Ghana-1.1, South Africa (SA)-3, Botswana-3.3 dermatologists per million population) in comparison to the rest of the world (United Kingdom-10, United States of America-36, Germany-65 dermatologists per million population). In Africa, less than one dermatologist is available per million population with the majority practising in urban areas [3]. The paucity in the number of dermatologists is concerning as dermatologic disease has substantial impact on long-term morbidity [4].

This analysis utilised the Health Professions Council of South Africa (HPCSA) database (from 2000 to 2019) with the variables: (i) category of health personnel (Specialty - Dermatology), (ii) geographical location, (iii) population category and (iv) sex. In this article, we have used the term population group in line with the definitions in the Population Registration Act (Act No. 30 of 1950) [5] which previously classified SA citizens into four major population categories - `White', `Coloured', `Indian' and `Black'. Although the legislation was repealed in 1991, population categories are still used in reporting in sectors such as the Department of Higher Education. Racialised data continue to be used in monitoring the redress in the education and training of dermatologists who were previously denied access to such training due to legislation. National databases such as Statistics SA and the HPCSA also segregate their data based on these same population groups. Assessment of privatisation of dermatology practices was undertaken by geographically mapping each dermatology private practice based on their area codes. This was compared with province-wide HPCSA registrations and with data procured from the General Household Survey regarding the medically insured population per province in 2019 [6]. Ethical approval was obtained from the Stellenbosch University Health Research Ethics Committee (HREC Reference No: X21/05/010).

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The data was analysed using the Statistical Package for the Social Sciences (SPSS version 22.0). For the analysis of training capacity and the supply pipeline, data was collected from the Colleges of Medicine of South Africa (CMSA) and the academic heads of dermatology divisions across SA universities. The deficit of dermatologists was forecasted using the DALY based method [7]. DALYs represents 'lost year of "healthy" life' thus measuring burden of disease. The DALY load per dermatologist was 1254 for SA (2019) which is comparatively lower than other African countries i.e. 1313 for Botswana (2021), 6085 for Namibia (2021) but higher than developed countries such as 814 for United Kingdom (2012) and 211 for USA (2015).

Total 264 dermatologists were registered (in nine provinces) of which 208 were of 65 years or below with the HPCSA in December 2019, amounting to 4.4 practising dermatologist (3.5 for dermatologists registered of 65 years or below) per million population. In the public sector the ratio is 1.2 dermatologists and in the private sector 20.1 dermatologists per million population. There is equal distribution of male and female dermatologists (50% each). Most dermatologists are practising in the more densely populated and urbanised areas with 78% operating in the private sector. The majority (50%) of dermatologists identified themselves as White, followed by Black (25%), Asian (18%), Coloured (3%) and 4% were unknown. Of the current trainee dermatologists, 49 are paid registrars who are state-funded whereas 15 are unpaid supernumerary registrars (non-South African (SA) registrars).

The aim was not to increase the number of dermatologists but to provide equitable access to dermatology services to the least performing provinces (high DALY load per dermatologist) and increasing the required number of dermatologists to the levels of better performing provinces (low DALY load per dermatologist) to achieve horizontal equity. The national shortfall was projected for 2030 to be (at least) within the range of 54-95 dermatologists.

The lack of dermatologists affects the public sector and less urbanised provinces to a greater degree. Among medical specialists, a wage differential of up to two times exists, which contributes to the SA dermatology workforce being inequitably distributed across provinces and public/private sectors. Thus, additional rural pay may incentivise retention of dermatologists in rural areas. Additional training of general practitioners and nurses in dermatological care and implementation of teledermatology programs is also recommended.

With enhanced and equitable implementation of human resources for health (HRH) planning [8], improved access to dermatological care may be achieved.

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Conflicts of interest: None to declare.

Figure legends

Figure 1: Status of dermatologists in South Africa, 2019 (dermatologists registered with 65 years of age or below)

Privatisation was assessed by geographically mapping each dermatology private practice based on area codes of their phone numbers. The number of dermatologists operating within the private sector were divided with the total registrations as per HPCSA (2019).

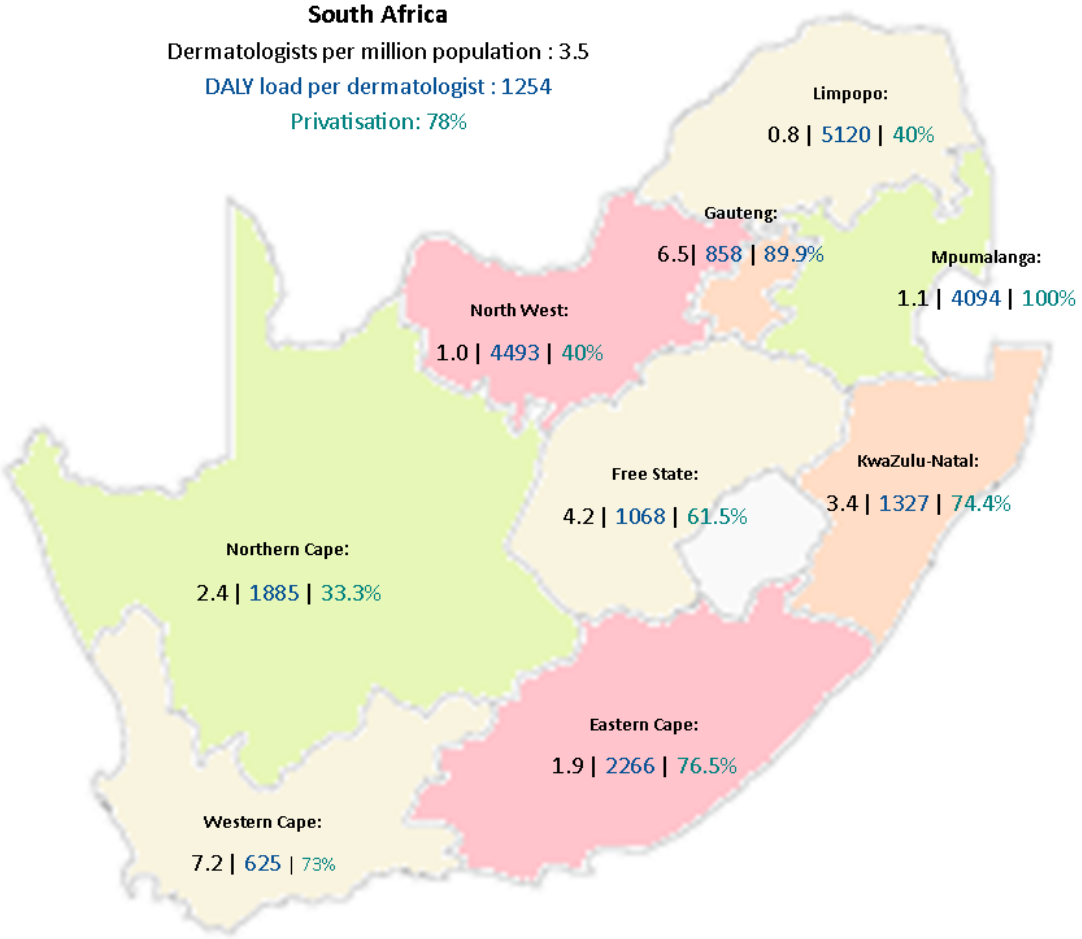

FIGURE KEY (LEGEND)

Province:
Dermatologists per million population | DALY load per dermatologist | Privatisation