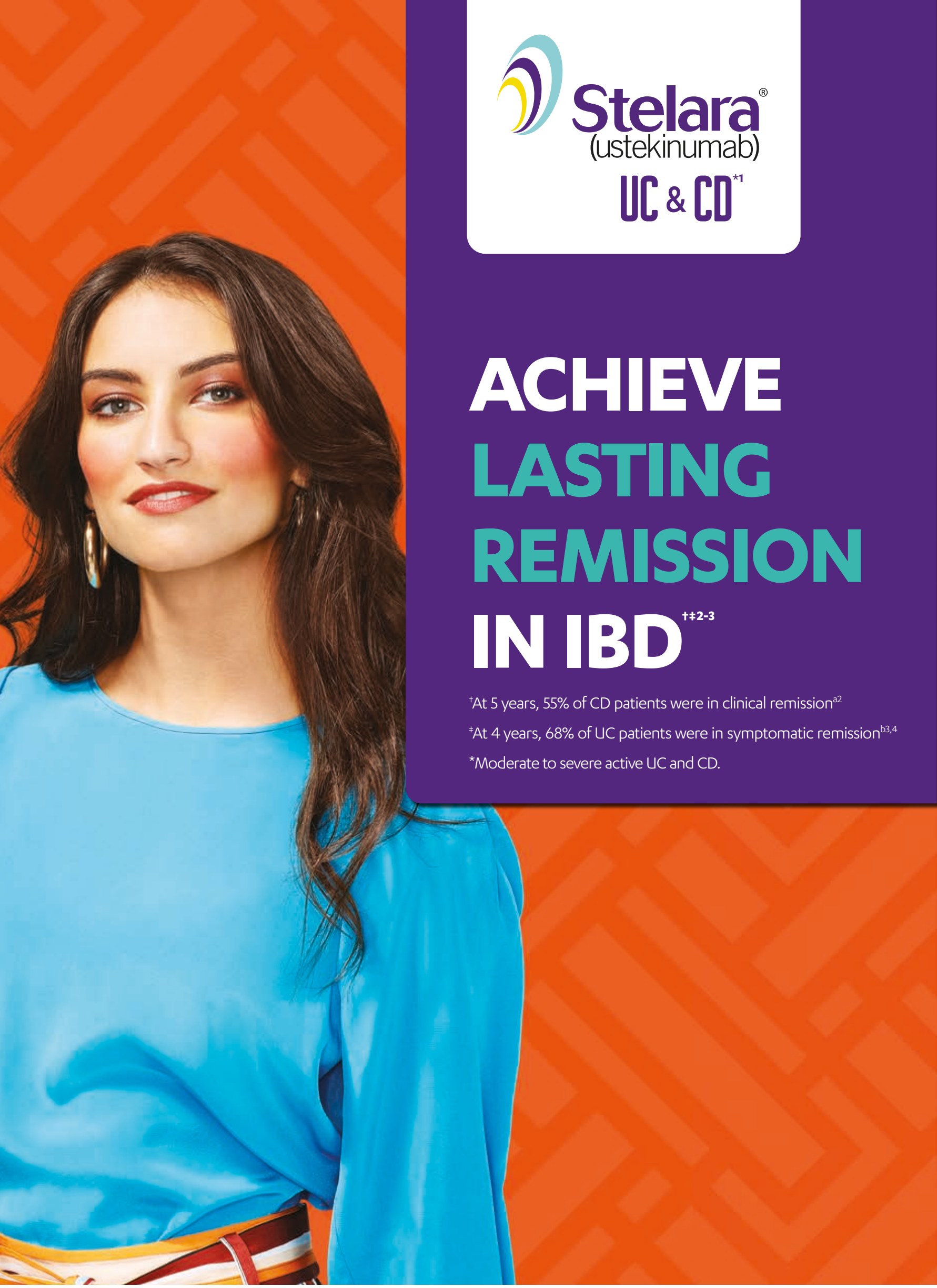

Stelara®
(ustekinumab)
UC & CD*[1]

# ACHIEVE LASTING REMISSION IN IBD[†‡2-3]

[†]At 5 years, 55% of CD patients were in clinical remission[a2]

[‡]At 4 years, 68% of UC patients were in symptomatic remission[b3,4]

*Moderate to severe active UC and CD.

[a] Randomised and non-randomised bionaïve STELARA 90 mg q8w patients in IM-UNITI LTE with CDAI <150 points (N=140).[2] [b]Randomised bionaïve STELARA 90 mg q8w patients in UNIFI LTE with Mayo stool frequency subscore of 0/1 and a rectal bleeding subscore of 0 (N=79).[3,4]

**References: 1.** Stelara Data Sheet. Available at: https://www.medsafe.govt.nz/profs/Datasheet/s/stelarainj.pdf. **2.** Sandborn WJ, et al. Clin. Gastroenterol Hepatol. 2022; 20(3): 578–590. **3.** Abreu M et al. J Crohns Colitis 2022; 16: 1222–1234. **4.** Afif W et al. United European Gastroenterology Week; October 3–5, 2022; Vienna, Austria. Abstract P0396.

**STELARA® ustekinumab (rmc) MINIMUM DATA SHEET.** STELARA® is a funded medicine for Crohn's Disease and Ulcerative Colitis – restrictions apply. For further details, see https://pharmac.govt.nz/pharmaceutical-schedule. **INDICATIONS: Plaque Psoriasis:** Moderate to severe Plaque Psoriasis in adults (18 years or older) who are candidates for photo- or systemic therapy. **Psoriatic Arthritis (PsA):** STELARA®, alone or in combination with methotrexate, is indicated for the treatment signs and symptoms, including reduction of the rate of progression of peripheral joint damage as measured by X-ray, of active Psoriatic Arthritis in adult patients (18 years or older). **Crohn's Disease:** Moderately to severely active Crohn's Disease in adult patients who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a TNF antagonist or have medical contraindications to such therapies. **Ulcerative Colitis:** Moderate to severely active ulcerative colitis in adult patients. **DOSE: Psoriasis:** Subcutaneous injection. 45 mg at Weeks 0 and 4, then every 12 weeks. Alternatively, in patients weighing >100 kg, 90 mg at Weeks 0 and 4, then every 12 weeks. If inadequate response, consider treatment every 8 weeks. Discontinue if no response after 28 weeks. **Psoriatic Arthritis:** Subcutaneous injection. 45 mg at Weeks 0 and 4, then every 12 weeks. Alternatively, in patients weighing >100 kg, 90 mg at Weeks 0 and 4, then every 12 weeks. **Crohn's Disease & Ulcerative Colitis:** Single initial intravenous tiered dose based on body weight using STELARA® 130 mg vial (weight ≤ 55kg = 260 mg [2 vials]; weight > 55kg to ≤ 85 kg = 390 mg [3 vials]; weight > 85 kg = 520 mg [4 vials]). Then subcutaneous injection of 90 mg 8 weeks after the intravenous dose, then every 8 weeks. In some patients a subcutaneous dose of 90 mg 8 weeks after the intravenous dose, then every 12 weeks may be acceptable according to clinical judgment. Consider discontinuing if no evidence of benefit by Week 16. Refer to full Data Sheet. **CONTRAINDICATIONS:** Hypersensitivity to ustekinumab or to any of the excipients. **PRECAUTIONS: Serious Infections**: STELARA® may increase risk of infections and reactivate latent infections. Serious bacterial, fungal and viral infections have been observed. Do not administer to patients with a clinically important active infection. Use with caution in patients with chronic or recurrent infections. **Tuberculosis (TB)**: Evaluate for TB prior to initiating treatment. Do not administer to patients with active TB. Treat latent TB before administration. Consider anti-TB therapy in patients with suspected TB. Monitor patients for TB. **Malignancies**: STELARA® may increase risk of malignancies. Malignancies have been observed. Use with caution in patients with known malignancy or history of malignancies. **Hypersensitivity Reactions**: Discontinue immediately if serious allergic reaction (including angioedema / anaphylaxis) occurs. **Immunisations**: Do not give live bacterial or viral vaccines. Consider secondary transmission of live vaccines from contacts. **Infant Exposure *in utero*:** Do not administer live vaccines to infants who have been exposed *in utero* for 6 months following birth, unless they are exposed in first trimester only, or if ustekinumab levels are undetectable in the infant or if benefit of vaccination outweighs risk. **Immunosuppression**: Use in caution with immunosuppressive agents or when transitioning from other biologic agents. **Immunotherapy:** Use with caution in patients receiving allergy immunotherapy. **Posterior Reversible Encephalopathy Syndrome (PRES)**: Monitor and if PRES is suspected, STELARA® should be discontinued and appropriate treatment administered. **Serious Skin Conditions:** Physicians should be alert for symptoms of erythrodermic psoriasis or exfoliative dermatitis in psoriasis patients. **General:** "Pre-filled syringe needle cover contains dry natural rubber (latex) which may cause allergic reactions. **Use in Pregnancy**: Category B1. **INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS:** Live vaccines should not be given concurrently with STELARA.; On initiation of STELARA® in patients receiving concomitant CYP450 substrates with a narrow therapeutic index, monitoring for therapeutic effect (e.g. for warfarin) or drug concentration (e.g. for cyclosporine) should be considered and the individual dose of the drug adjusted as needed. See full Data Sheet. **ADVERSE EFFECTS:** Upper respiratory tract infections; nasopharyngitis; dizziness; headache; oropharyngeal pain; diarrhoea; nausea; vomiting; pruritus; back pain; myalgia; arthralgia; fatigue; injection site erythema; injection site pain, serious infections, sinus infection; malignancies; depression and suicidality; hypersensitivity reactions including anaphylaxis and angioedema. See full Data Sheet. **Medicine Classification:** Prescription Medicine. **PRESENTATION:** STELARA® is a Prescription Medicine containing ustekinumab in packs of 1 single use 45mg pre-filled syringe; or 90mg pre-filled syringe each for subcutaneous use. For initiation dose in Crohn's Disease and Ulcerative Colitis only: A pack of 1 single use 130 mg/5 mL vial for intravenous infusion. **STORAGE:** Store at 2°C – 8°C. Refrigerate. Do not freeze or shake. Protect from light by storing in original carton. If needed, STELARA® pre-filled syringes can be stored at room temperature up to 30°C for one period of time up to 30 days, not exceeding the original expiry. Before prescribing, please review full Data Sheet available from https://www.janssen.com/newzealand/sites/www_janssen_com_newzealand/files/prod_files/live/stelar a_data_sheet.pdf or www.medsafe.govt.nz. Janssen-Cilag (New Zealand) Ltd, 507 Mount Wellington Hwy, Mount Wellington, Auckland 1060, New Zealand. Date of preparation: 29 August 2024. Material Preparation Date: November 2024. CP-442232. TAPS NP21827. INSIGHT 13250

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