Maklumat tambahan indikasi
Year 2017
Products Approved For Additional Indication (DCA 317 – 30 October 2017)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **SIMPONI SOLUTION FOR INJECTION** [Golimumab 50mg/0.5ml]	➢ Indication: ***Non-radiographic axial spondyloarthritis (nr-Axial SpA)*** *SIMPONI, by subcutaneous (SC) administration, is indicated for the treatment of adult with severe, active non radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/ or magnetic resonance imaging (MRI) evidence, who have inadequate response to, or are intolerant to non steroidal anti-inflammatory drugs (NSAIDs)* ➢ Posology: ***SIMPONI®** Solution for Injection* ***Subcutaneous injection*** *Rheumatoid arthritis:* *SIMPONI 50 mg given once a month, on the same date each month.* *SIMPONI should be given concomitantly with MTX.* *Psoriatic arthritis, ankylosing spondylitis or non-radiographic axial spondyloarthritis:* *SIMPONI 50 mg given once a month, on the same date each month.* *For all of the above indications, available data suggest that clinical response is usually achieved within 12 to 14 weeks of treatment (after 3-4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period.* *Patients with bodyweight greater than 100 kg* *For all of the above indications, in patients with RA, PsA or AS, or nr-Axial SpA with a body weight of more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse drug reactions with the 100 mg dose compared with the 50 mg dose. Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit after receiving 3 to 4 additional doses of 100 mg.* *Ulcerative colitis:*	**Johnson & Johnson Sdn Bhd** Lot 3 & 5, Jalan Tandang 46050 Petaling Jaya Selangor

Patients with body weight less than 80 kg
SIMPONI given as an initial dose of 200 mg, followed by 100 mg at week 2, then 50 mg every 4 weeks, thereafter

Patients with body weight greater than or equal to 80 kg
SIMPONI given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks, thereafter

During maintenance treatment, corticosteroids may be tapered in accordance with clinical practice guidelines.

Available data suggest that clinical response is usually achieved within 12-14 weeks of treatment (after 4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period.

Missed dose
If a patient forgets to inject SIMPONI on the planned date, the forgotten dose should be injected as soon as the patient remembers. Patients should be instructed not to inject a double dose to make up for the forgotten dose.

The next dose should be administered based on the following guidance:
• if the dose is less than 2 weeks late, the patient should inject his/her forgotten dose and stay on his/her original schedule.
• if the dose is more than 2 weeks late, the patient should inject his/her forgotten dose and a new schedule should be established from the date of this injection.

Special populations

Elderly (≥ 65 years)
No dosage adjustment is required in the elderly.

Renal and hepatic impairment
SIMPONI has not been studied in these patient populations. No dose recommendations can be made.

Paediatric patients
The safety and efficacy of SIMPONI in patients aged less than 18 have not yet been established. No data are available.

Method of administration
Subcutaneous injection
SIMPONI® Solution for Injection is for subcutaneous use.

		After proper training in subcutaneous injection technique, patients may self-inject with SIMPONI® Solution for Injection if their physician determines that this is appropriate, with medical follow-up as necessary. Patients should be instructed to inject the full amount of SIMPONI® Solution for Injection according to the comprehensive instructions for administration provided in the package leaflet. If multiple injections are required, the injections should be administered at different sites on the body.	