Maklumat tambahan indikasi untuk upload pada laman web
Year 2015
Products Approved For Additional Indication (DCA 290 – 3 Ogos 2015)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **SIMPONI 50MG (0.5ML) SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE** [Golimumab 100mg/ml (two fill volumes available: 0.5ml and 1ml)]	➢ Indication: *Ulcerative colitis (UC)* *Simponi is indicated for the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.* ➢ Posology: *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.*	**JOHNSON & JOHNSON SDN BHD** Lot 3 & 5, Jalan Tandang 46050 Petaling Jaya, Selangor

2.	2.1 **SOMATULINE AUTOGEL 120MG, PROLONGED-RELEASE SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE** [Lanreotide acetate 142.96mg (equivalent to lanreotide base 120mg)]	➢ Indication: *<u>Somatuline® Autogel® 120 mg</u>* *The treatment of grade 1 and a subset of grade 2 (Ki67 index up to 10%) gastroenteropancreatic neuroendocrine tumours (GEP-NETs) of midgut, pancreatic or unknown origin where hindgut sites of origin have been excluded, in adult patients with unresectable locally advanced or metastatic disease.* ➢ Posology: *Gastroenteropancreatic Neuroendocrine Tumours* *The recommended dose of SOMATULINE AUTOGEL is 120 mg administered every 4 weeks by deep subcutaneous injection. There is no recommended dose adjustment for mild or moderate renal impairment. There is insufficient information to recommend a dose for patients with severe renal impairment or with hepatic impairment of any severity.*	**A. MENARINI SINGAPORE PTE. LTD.** Level 2, No. 10 Jalan Bersatu 13/4 46200 Petaling Jaya, Selangor
3	3.1 **Jakavi 5mg Tablets** [Ruxolitinib Phosphate 5mg] 3.2 **Jakavi 15mg Tablets** [Ruxolitinib Phosphate 15mg] 3.3 **Jakavi 20mg Tablets** [Ruxolitinib Phosphate 20mg]	➢ Indication: *<u>Polycythaemia vera (PV)</u>* *Jakavi is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.* ➢ Posology: *Starting Dose* *The recommended starting dose of Jakavi in polycythaemia vera is 10mg given orally twice daily.* *Dose Modifications* *In PV, treatment should also be interrupted when haemoglobin is below 8g/dl.* *In PV, dose reductions should also be considered if haemoglobin decreases below 12g/dl and is recommended if it decreases below 10g/dl.*	**NOVARTIS CORPORATION (MALAYSIA) SDN BHD** Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan Seksyen 13 46200 Petaling Jaya, Selangor

		If efficacy is considered insufficient and blood counts are adequate, doses may be increased by a maximum of 5mg twice daily, up to the maximum dose of 25mg twice daily. *Special Populations* *Renal Impairment* *The recommended starting dose for PV patients with severe renal impairment is 5mg twice daily.* *The recommended starting dose for PV patients with ESRD on haemodialysis is a single dose of 10mg or two doses of 5mg given 12 hours apart, to be administered post-dialysis and only on the day of haemodialysis.*	