Maklumat tambahan indikasi
Year 2018
Products Approved For Additional Indication (DCA 319 – 4 Januari 2018)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **GAZYVA 1000 MG/ 40 ML CONCENTRATE FOR SOLUTION FOR INFUSION** [OBINUTUZUMAB 1000MG/40ML]	➢ Posology: *Follicular Lymphoma* *Gazyva in combination with bendamustine followed by Gazyva maintenance is indicated for the treatment of patients with follicular lymphoma (FL) who did not respond or who progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen.* *Standard dose* *Follicular Lymphoma* *Induction Treatment (in combination with bendamustine[2]):* *The recommended dosage of Gazyva is 1000 mg administered on Day 1, Day 8 and Day 15 of the first 28 day treatment cycle followed by 1000 mg administered on Day 1 only for each subsequent 28 day treatment cycle (Cycles 2 to 6) as shown in Table 3.* *Maintenance Treatment:* *Patients who respond to induction treatment (i.e. the initial 6 treatment cycles) or have stable disease should continue to receive Gazyva 1000 mg alone as maintenance therapy once every 2 months until disease progression or for up to two years (whichever occurred first).*	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway 47500 Subang Jaya, Selangor

		Table 3 Dose and Infusion rate of Gazyva for patients with FL <table><tr><th colspan="2">Day of treatment cycle</th><th>Dose of Gazyva</th><th>Rate of infusion If an infusion related reaction occurs, adjust infusion as outlined in Table 4</th></tr><tr><td>Cycle 1</td><td>Day 1</td><td>1000 mg</td><td>Administer at 50 mg/hr. The rate of infusion can be escalated in 50 mg/hr increments every 30 minutes to a maximum of 400 mg/hr.</td></tr><tr><td></td><td>Day 8</td><td>1000 mg</td><td rowspan="4">If no infusion related reaction occurred during the previous infusion where the final infusion rate was ≥100 mg/hr, infusions can be started at a rate of 100 mg/hr and increased by 100 mg/hr increments every 30 minutes to a maximum of 400 mg/hr.</td></tr><tr><td></td><td>Day 15</td><td>1000 mg</td></tr><tr><td>Cycles 2–6</td><td>Day 1</td><td>1000 mg</td></tr><tr><td>Maintenance</td><td>Every two months until progression or up to two years</td><td>1000 mg</td></tr></table>[2] See section *3.1.2 Clinical/Efficacy Studies [3.1 Pharmacodynamic Properties]* for information on bendamustine dose *Delayed or missed doses* *If a planned dose of Gazyva is missed, it should be administered as soon as possible; do not wait until the next planned dose. During induction, the planned treatment interval for Gazyva should be maintained between doses. During maintenance, maintain the original dosing schedule for subsequent doses.*	
2.	2.1 **ADCETRIS 50MG, POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION** [BRENTUXIMAB VEDOTIN 50MG]	➢ Indication: *Adcetris is indicated for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin lymphoma (HL):* *1. following autologous stem cell transplant (ASCT) or*	**TAKEDA MALAYSIA SDN BHD.** Unit TB-L 13-1, Level 13, Tower B, Plaza 33

		2. *following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option.* *Adcetris is indicated for the treatment of adult patients with CD30+ HL at increased risk of relapse or progression following ASCT.* *Adcetris is indicated for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL).*	No.1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor