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Year 2013
Products Approved For Additional Indication (DCA 267 – 29 Ogos 2013)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **VELCADE (BORTEZOMIB) FOR INJECTION** [Bortezomib 3.5mg]	➢ Posology: *The recommended starting dose of Velcade is 1.3mg/m^2. Velcade may be administered intravenously at a concentration of 1 mg/ml, or subcutaneously at a concentration of 2.5 mg/ml. When administered intravenously, Velcade is administered as a 3 to 5 second bolus intravenous injection. Velcade is for intravenous of subcutaneous use only. Velcade should not be administered by any other route.* *Because each route of administration has a different reconstituted concentration, caution should be used when calculation the volume to be administered.* *Dosage in Previously Untreated Multiple Myeloma* *Velcade (bortezomib) is administered in combination with oral mephalan and oral prednisone for nine 6-week treatment cycles as shown in Table 1. In Cycles 1 – 4, Velcade is administered twice weekly (days 1, 4, 8, 11, 22, 25, 29 and 32). In Cycles 5 – 9, Velcade is administered once weekly (days 1, 8, 22 and 29). At least 72 hours should elapse between consecutive doses of Velcade.* *Dosage in Relapsed Multiple Myeloma and Mantle Cell Lymphoma* *Velcade (1.3 mg/m2/dose) is administered twice weekly for 2 weeks (Days 1, 4, 8, and 11) followed by a 10-day rest period (Days 12 - 21). For extended therapy of more than 8 cycles, Velcade may be administered on the standard schedule or*	**JOHNSON & JOHNSON SDN BHD** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor.

		on a maintenance schedule of once weekly for 4 weeks (Days 1, 8, 15, and 22) followed by a 13-day rest period (Days 23 to 35). At least 72 hours should elapse between consecutive doses of Velcade. *Administration* *Velcade is administered intravenously or subcutaneously. Velcade is administered as a 3 - 5 second bolus intravenous injection through a peripheral or central intravenous catheter followed by a flush with 0.9% sodium chloride solution for injection. For subcutaneous administration, the reconstituted solution is injected into the thighs (right or left) or abdomen (right or left). Injection sites should be rotated for successive injections. If local injection site reactions occur following Velcade injection subcutaneously, a less concentrated Velcade solution (1 mg/ml instead of 2.5 mg/ml) may be administered subcutaneously , or changed to IV injection.* *VELCADE IS FOR INTRAVENOUS OR SUBCUTANEOUS USE ONLY. Intrathecal administration has resulted in death.*	
2.	2.1 **Certican 0.1 mg Dispersible Tablet** [Everolimus 0.1 mg] 2.2 **Certican 0.25 mg Dispersible Tablet** [Everolimus 0.25 mg] 2.3 **Certican 0.25 mg Tablets** [Everolimus 0.25 mg] 2.4 **Certican 0.5 mg Tablets** [Everolimus 0.5 mg] 2.5 **Certican 0.75 mg Tablets** [Everolimus 0.75 mg] 2.6 **Certican 1.0 mg Tablets** [Everolimus 1.0 mg]	➢ Indication: *Kidney and heart transplantation* *Certican is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal or cardiac transplant. In kidney and heart transplantation, Certican should be used in combination with ciclosporin for microemulsion and corticosteroids.* *Liver transplantation* *Certican is indicated for the prophylaxis of organ rejection in patients receiving a hepatic transplant. In liver transplantation, Certican should be used in combination with tacrolimus and corticosteroids.*	**NOVARTIS CORPORATION (MALAYSIA) SDN BHD** Level 15, CREST, 3 Two Square No. 2, Jalan 19/1 46300 Petaling Jaya, Selangor

		➢ Posology: *Adults* *An initial dose regimen of 0.75 mg b.i.d., which is recommended for the general kidney and heart transplant population, should be administered as soon as possible after transplantation. The dose of 1.0 mg b.i.d is recommended for the hepatic transplant population with the initial dose approximately 4 weeks after transplantation. The daily dose of Certican should always be given orally in two divided doses (b.i.d.). Certican should be consistently given either with or without food and at the same time as ciclosporin for microemulsion or tacrolimus.* *Black patients* *The incidence of biopsy-proven acute rejection episodes was significantly higher in black renal transplant patients than in non-black patients. Limited information indicates that black patients, may require a higher Certican dose to achieve efficacy similar to that achieved in non-black patients at the recommended adult dose. Currently, the efficacy and safety data are too limited to allow specific recommendations for use of everolimus in black patients.* *Therapeutic Drug Monitoring* *Routine whole blood therapeutic drug level monitoring of everolimus is recommended. Based on exposure-efficacy and exposure-safety analysis, patients achieving everolimus whole blood trough levels (C0) ≥3.0 ng/mL have been found to have a lower incidence of biopsy-proven acute rejection in renal, cardiac and hepatic transplantation than patients whose trough levels (C0) are below 3.0 ng/mL. The recommended upper limit of the therapeutic range is 8 ng/mL. Exposure above 12 ng/mL has not been studied. These recommended ranges for everolimus are based on*	

		chromatographic methods. *Tacrolimus dose recommendation in hepatic transplantation* *Hepatic transplant patients should have the tacrolimus exposure reduced to minimize calcineurin related renal toxicity. The tacrolimus dose should be reduced starting approximately 3 weeks after initiation of dosing in combination with Certican based on tacrolimus blood trough levels (C0) targeting 3-5 ng/mL. Certican has not been evaluated with full dose tacrolimus in controlled clinical trials.*	