

**Maklumat tambahan indikasi untuk upload pada laman web
Year 2015**

Products Approved For Additional Indication (DCA 292 – 28 September 2015)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	<p>1.1 KOGENATE-FS 250 IU [Antihemophilic Factor [Recombinant] Formulated with Sucrose 250 IU/ 2.5mL]</p> <p>1.2 KOGENATE-FS 500 IU [Antihemophilic Factor [Recombinant] Formulated with Sucrose 500 IU/ 2.5mL]</p> <p>1.3 KOGENATE-FS 1000 IU [Antihemophilic Factor [Recombinant] Formulated with Sucrose 1000 IU/ 2.5mL]</p>	<p>➤ Indication:</p> <p><i>Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes in adults with haemophilia A.</i></p> <p>➤ Posology:</p> <p><i>For routine prophylaxis in adults: The recommended dose for routine prophylaxis is 25 units per kg of body weight three times per week.</i></p>	<p>BAYER CO. (M) SDN BHD T1-14 Jaya 33, No 3 Jalan Semangat Seksyen 13, 46200 Petaling Jaya, Selangor, Malaysia</p>
2	<p>2.1 AVASTIN INJECTION 25 MG/ML [Bevacizumab 25mg/ml]</p>	<p>➤ Indication:</p> <p><i>Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer</i></p> <p><i>Avastin, in combination with carboplatin and paclitaxel is indicated for the front-line treatment of advanced (FIGO* stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer.</i></p> <p><i>Avastin, in combination with carboplatin and gemcitabine is indicated for the treatment of patients with recurrent, platinum-sensitive, epithelial ovarian, fallopian tube, or primary peritoneal cancer who have not received prior bevacizumab or other VEGF*-targeted angiogenesis inhibitors.</i></p> <p><i>Avastin in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin is indicated for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents.</i></p> <p><i>*FIGO : International Federation of Gynaecology and Obstetrics</i></p>	<p>ROCHE (MALAYSIA) SDN BHD Level 21, The Pinnacle, Persiaran Lagoan Bandar Sunway 47500 Subang Jaya, Selangor</p>

		<p><i>*VEGF: Vascular Endothelial Growth Factor</i></p> <p>➤ Posology:</p> <p><i>The recommended dose of Avastin is 15 mg/kg of body weight given once every 3 weeks as an intravenous infusion.</i></p> <p><i>Front-line treatment:</i> <i>Avastin is administered in addition to carboplatin and paclitaxel for up to six cycles of treatment followed by continued use of Avastin as single agent for 15 months or until disease progression, whichever occurs earlier.</i></p> <p><i>Treatment of recurrent disease:</i></p> <p><i>Platinum-sensitive</i> <i>Avastin is administered in combination with carboplatin and gemcitabine for 6 cycles and up to 10 cycles followed by continued use of Avastin as single agent until disease progression.</i></p> <p><i>Platinum resistant</i> <i>10mg/kg body weight given once every 2 weeks when administered in combination with one of the following agents- paclitaxel, topotecan (given weekly) or pegylated liposomal doxorubicin.</i> <i>Alternatively, 15mg/kg every 3 weeks when administered in combination with topotecan given on days 1-5, every 3 weeks.</i> <i>It is recommended that treatment be continued until disease progression.</i></p>	
3.	<p>3.1 KIOVIG 100MG/ML SOLUTION FOR INFUSION [Human normal immunoglobulin 100mg/ml]</p>	<p>➤ Indication:</p> <p><i>Multifocal Motor Neuropathy (MMN)</i></p> <p>➤ Posology:</p> <p><i>Starting dose: 2g/kg for 2-5 days</i> <i>Maintenance dose: 1g/kg every 2 to 4 weeks or 2g/kg every 4-8 weeks</i></p>	<p>BAXTER HEALTHCARE (M) SDN. BHD Suite 7.01, Level 7 The Gardens, South Tower Mid Valley City 59200 Kuala Lumpur, Malaysia</p>