

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

Products Approved For Additional Indication (DCA 291 – 20 Ogos 2015)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	<p>1.1 GLYPRESSIN 1MG INJECTION [Terlipressin acetate 1mg equivalent to 0.86mg terlipressin free base]</p>	<p>➤ Indication: <i>Treatment of type 1 hepatorenal syndrome, characterised by spontaneous acute renal insufficiency, in patients suffering from severe cirrhosis with ascites.</i></p> <p>➤ Posology: <i>Type 1 hepatorenal disease 3 to 4 mg of terlipressin every 24 hours as 3 or 4 administrations. In the absence of any reduction of the serum creatinine after 3 days of treatment, cessation of GLYPRESSIN treatment is advised. In the other cases, GLYPRESSIN treatment is to be pursued until the obtaining either of a serum creatinine less than 130 µmol/litre or of a drop of at least 30% in serum creatinine with respect to the value measured at the time of diagnosis of hepatorenal syndrome. The standard average duration of treatment is 10 days.</i></p>	<p>FERRING SDN. BHD. 21-6, Block B Jaya One No 72A, Jalan Universiti 46200 Petaling Jaya, Selangor</p>
2	<p>2.1 Exforge 5mg/80mg Film-Coated Tablet [Amlodipine 5mg/ Valsartan 80mg]</p> <p>2.2 Exforge 5mg/160mg Film-Coated Tablet [Amlodipine 5mg/ Valsartan 160mg]</p> <p>2.3 Exforge 5mg/320mg Film-Coated Tablet [Amlodipine 5mg/ Valsartan 320mg]</p> <p>2.4 Exforge 10mg/160mg Film-Coated Tablet [Amlodipine 10mg/ Valsartan 160mg]</p> <p>2.5 Exforge 10mg/320mg Film-Coated Tablet [Amlodipine 10mg/ Valsartan 320mg]</p>	<p>➤ Indication: <i>Exforge is indicated for the initial treatment of hypertension. The choice of Exforge for initial treatment should be based on an assessment of the potential benefits and risks.</i></p> <p>➤ Posology: <i>For initial therapy the usual starting dose is Exforge 5mg/80mg once daily. The dosage can be increased after 1 to 2 weeks of therapy to a maximum of 10mg/320mg per day as needed to control blood pressure. Exforge is not recommended as initial therapy in patients with intravascular volume depletion. The maximum dose is 10mg/320mg per day.</i></p>	<p>NOVARTIS CORPORATION (MALAYSIA) SDN BHD Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan Seksyen 13 46200 Petaling Jaya, Selangor</p>