

Maklumat tambahan indikasi untuk upload pada laman web

Year 2014

Products Approved For Additional Indication (DCA 279 – 28 Ogos 2014)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	<p>1.1 XOLAIR 150MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION [Omalizumab 150mg per 1.2mL reconstituted solution (125mg/mL)]</p>	<p>➤ Indication:</p> <p><i>Xolair is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.</i></p> <p>➤ Posology:</p> <p><i>Dosage for Chronic Spontaneous Urticaria (CSU) The recommended dose is 300 mg by subcutaneous injection every four weeks. Some patients may achieve control of their symptoms with a dose of 150 mg every four weeks.</i></p> <p><i>Paediatric patients In chronic spontaneous urticaria, safety and efficacy in pediatric patients below the age of 12 years have not been established.</i></p>	<p>NOVARTIS CORPORATION (M) SDN BHD Level 22, Tower B, Plaza 33 No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor</p>
2.	<p>2.1 NEVANAC OPHTHALMIC SUSPENSION 0.1% [Nepafenac 0.1% w/v]</p>	<p>➤ Indication:</p> <p><i>Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.</i></p> <p>➤ Posology:</p> <p><i>For the reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients, the dose is 1 drop of Nevanac in the conjunctival sac of the affected eye(s) 3 times daily beginning 1 day prior to cataract surgery, continued on the day of surgery and up to 60 days of the postoperative period as directed by the clinician. An additional drop should be administered 30 to 120 minutes prior to surgery.</i></p>	<p>ALCON LABORATORIES (MALAYSIA) SDN. BHD. No. 1001A & 1001D, 9th Floor Wisma Glomac 3 Kompleks Kelana Centre Point No. 3, Jalan Ss7/19, Kelana Jaya 47301 Petaling Jaya, Selangor</p>

3.	<p>3.1 Galvus 50mg Tablet [Vildagliptin 50mg]</p>	<p>➤ Indication:</p> <p><i>Vildagliptin is also indicated as initial combination therapy with metformin in patients with T2DM whose diabetes is not adequately controlled by diet and exercise alone.</i></p> <p>➤ Posology:</p> <p><i>When used as initial combination therapy with metformin, the recommended dose of Galvus is 50mg once or twice daily.</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>
4.	<p>4.1 Galvus Met 50/500mg Film Coated Tablet [Vildagliptin 50mg/ Metformin 500mg]</p> <p>4.2 Galvus Met 50/850mg Film Coated Tablet [Vildagliptin 50mg/ Metformin 850mg]</p> <p>4.3 Galvus Met 50/1000mg Film Coated Tablet [Vildagliptin 50mg/ Metformin 1000mg]</p>	<p>➤ Indication:</p> <p><i>Galvus Met is also indicated as initial therapy in patients with T2DM whose diabetes is not adequately controlled by diet and exercise alone.</i></p> <p>➤ Posology:</p> <p><i>For treatment naive patients, Galvus Met may be initiated at 50mg/500mg once daily and gradually titrated to a maximum dose of 50mg/1000mg twice daily after assessing adequacy of therapeutic response.</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>