

Maklumat tambahan indikasi untuk upload pada laman web

Year 2012

Products Approved For Additional Indication (DCA 256 – 27 September 2012)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	<p>1.1 <b>Alimta Injection 100mg</b> [ Pemetrexed 100mg]</p> <p>1.2 <b>Alimta 500mg Injection</b> [ Pemetrexed 500mg]</p>	<p>➤ Indication:</p> <p><i>ALIMTA is indicated as monotherapy for the maintenance treatment of local advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy.</i></p> <p>➤ Posology:</p> <p><i>- No change to posology</i></p>	<p><b>ELI LILLY (MALAYSIA) SDN. BHD.</b> Unit 18.1, Level 18, CP Tower, No 11, Jalan 16/11, Pusat Dagang Seksyen 16, 46350 Petaling Jaya, Selangor Darul Ehsan.</p>
2.	<p>2.1 <b>Coralan 5mg film-coated tablets</b> [Ivabradine hydrochloride 5.39mg (equivalent to ivabradine 5mg)]</p> <p>2.2 <b>Coralan 7.5mg film-coated tablets</b> [Ivabradine hydrochloride 8.085 mg (equivalent to ivabradine 7.5mg)]</p>	<p>➤ Indication:</p> <p><u><i>Treatment of Chronic Heart Failure</i></u> <i>Ivabradine is indicated in chronic heart failure NYHA II to IV class with systolic dysfunction, in patients with sinus rhythm and whose heart rate is ≥ 75 bpm, in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated.</i></p> <p>➤ Posology:</p> <p><u><i>Treatment of chronic heart failure</i></u> <i>The treatment has to be initiated only in patient with stable heart failure. It is recommended that the treating physician should be experienced in management of chronic heart failure.</i></p> <p><i>The usual recommended starting dose of ivabradine</i></p>	<p><b>SERVIER MALAYSIA SDN. BHD.</b> 1301, Level 13, Uptown 2, Damansara Utama, 47400 Petaling Jaya, Selangor.</p>

		<p><i>is 5mg twice daily. After two weeks of treatment, the dose can usually be increased to 7.5mg twice daily if resting heart rate is persistently above 60bpm or decreased to 2.5mg twice daily (one half 5mg tablet twice daily) if resting heart rate is persistently below 50 bpm or in case of symptoms related to bradycardia such as dizziness, fatigue or hypotension.</i></p> <p><i>If heart rate is between 50 and 60 bpm, the dose of 5mg twice daily should be maintained.</i></p> <p><i>If during treatment, heart rate decreases persistently below 50 beats per minute (bpm) at rest or the patient experiences symptoms related to bradycardia, the dose must be titrated downward to the next lower dose in patients receiving 7.5 mg twice daily. If the heart rate increases persistently above 60 beats per minute at rest, the dose can be up titrated to the next upper dose in patients receiving 2.5mg twice daily or 5mg twice daily.</i></p> <p><i>Treatment must be discontinued if the heart rate remains below 50bpm or symptoms of bradycardia persist.</i></p>	
3.	<p>3.1 <b>Genotropin® 5.3 mg Powder And Solvent For Solution For Injection</b> [ Somatropin 5.3 mg / mL]</p> <p>3.2 <b>Genotropin® 12 mg Powder And Solvent For Solution For Injection</b> [ Somatropin 12 mg / mL]</p>	<p>➤ Indication:</p> <p><i>Children Growth disturbance associated with chronic renal insufficiency.</i></p>	<p><b>PFIZER (M) SDN BHD</b> Level 3 &amp; 4, Bangunan Palm Grove, No. 14, Jalan Glenmarie (Persiaran Kerjaya), Section U1, 40150 Shah Alam, Selangor.</p>

4.	<b>4.1 Menactra Solution For Injection</b> <u>[ 1 dose (0.5ml) contains:</u>  Purified Meningococcal Polysaccharide Group A 4mcg Purified Meningococcal Polysaccharide Group C 4mcg Purified Meningococcal Polysaccharide Group Y 4mcg Purified Meningococcal Polysaccharide Group W135 4mcg ]	➤ Indication:  <i>active immunisations of individuals of 9 months through 23 months of age for the prevention of invasive meningococcal disease caused by N meningitidis serogroups A, C, Y and W-135.</i>	<b>SANOPI-AVENTIS (MALAYSIA) SDN. BHD.</b> 8th Floor, PNB Damansara, No. 19, Lorong Dungun, Damansara Heights, 50490 Kuala Lumpur.
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