

Maklumat tambahan indikasi untuk upload pada laman web
Year 2016

Products Approved For Additional Indication (DCA 305 – 31 Oktober 2016)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	<p>1.1 Eligard 7.5mg Powder & Solvent for Solution For Injection [7.5 mg leuprorelin acetate, equivalent to 6.96 mg leuprorelin]</p> <p>1.2 Eligard 22.5mg Powder & Solvent for Solution For Injection [22.5 mg leuprorelin acetate, equivalent to 20.87 mg leuprorelin]</p> <p>1.3 Eligard 45mg Powder & Solvent for Solution For Injection [45 mg leuprorelin acetate, equivalent to 41.7 mg leuprorelin]</p>	<p>➤ Indication:</p> <p><i>ELIGARD is indicated for the treatment of high-risk localized and locally advanced hormone dependent prostate cancer in combination with radiotherapy.</i></p> <p>➤ Posology:</p> <p><i>ELIGARD may be used as neoadjuvant or adjuvant therapy in combination with radiotherapy in high-risk localised and locally advanced prostate cancer.</i></p> <p><i>Paediatric population</i> <i>Safety and efficacy in children under the age of 18 years have not been established.</i></p>	<p>DKSH MALAYSIA SDN. BHD. B-11-01, The Ascent, Paradigm No. 1, Jalan SS7/26A, Kelana Jaya 47301 Petaling Jaya, Selangor</p>
2.	<p>2.1 Cosentyx 150mg Powder for solution for injection [Secukinumab 150mg/vial]</p> <p>2.2 Cosentyx 150mg/ml solution for injection in pre-filled pen [Secukinumab 150mg/vial]</p> <p>2.3 Cosentyx 150mg/ml solution for injection in pre-filled syringe [Secukinumab 150mg/vial]</p>	<p>➤ Indication:</p> <p><i>Ankylosing spondylitis</i> <i>Cosentyx is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.</i></p> <p>➤ Posology:</p> <p><i>Ankylosing spondylitis</i> <i>The recommended dose is 150mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4.</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>

3.	<p>3.1 SYNFLORIX VACCINE [1 dose (0.5ml) contains:</p> <ul style="list-style-type: none"> 1 mcg Streptococcus (S) Pneumonia polysaccharide serotype 1^{1,2} 3 mcg S. Pneumonia polysaccharide serotype 4^{1,2} 1 mcg S. Pneumonia polysaccharide serotype 5^{1,2} 1 mcg S. Pneumonia polysaccharide serotype 6B^{1,2} 1 mcg S. Pneumonia polysaccharide serotype 7F^{1,2} 1 mcg S. Pneumonia polysaccharide serotype 9V^{1,2} 1 mcg S. Pneumonia polysaccharide serotype 14^{1,2} 3 mcg S. Pneumonia polysaccharide serotype 18C^{1,3} 3 mcg S. Pneumonia polysaccharide serotype 19F^{1,4} 1 mcg S. Pneumonia polysaccharide serotype 23F^{1,2} <p>¹ adsorbed on aluminium phosphate ² conjugated to protein D (derived from NTHi) carrier protein ³ conjugated to tetanus toxoid carrier protein ⁴ conjugated to diphtheria toxoid carrier protein]</p>	<p>➤ Indication:</p> <p><i>Active immunisation of infants and children from 6 weeks up to 5 years of age against disease caused by Streptococcus pneumoniae serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F and cross-reactive serotype 19A (including sepsis, meningitis, pneumonia, bacteraemia and acute otitis media) and against acute otitis media caused by Non-Typeable Haemophilus influenza.</i></p>	<p>GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD. Level 6, Quill 9, 112, Jalan Semangat No.8, Persiaran Tropicana 46300 Petaling Jaya, Selangor</p>
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