Maklumat tambahan indikasi untuk upload pada laman web
Year 2012
Products Approved For Additional Indication (DCA 252 – 31 MEI 2012)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Prevenar 13 Suspension For Injection** [1 dose (0.5ml) contains Pneumococcal polysaccharide serotype 11 2.2µg Pneumococcal polysaccharide serotype 31 2.2µg Pneumococcal polysaccharide serotype 41 2.2µg Pneumococcal polysaccharide serotype 6A1 2.2µg Pneumococcal polysaccharide serotype 6B1 4.4µg Pneumococcal polysaccharide serotype 7F1 2.2µg Pneumococcal polysaccharide serotype 9V1 2.2µg Pneumococcal polysaccharide serotype 141 2.2µg Pneumococcal polysaccharide serotype 18C1 2.2µg Pneumococcal polysaccharide serotype 19A1 2.2µg Pneumococcal polysaccharide serotype 19F1 2.2µg Pneumococcal polysaccharide serotype 23F1 2.2µg 1Conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate (0.125mg aluminium)]	➢ Active immunisation for the prevention of pneumococcal disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults aged 50 years and older. This indication is based on immune responses elicited by Prevenar 13 and there have been no controlled trials in adults demonstrating vaccine efficacy.	**PFIZER (M) SDN BHD** Level 3 & 4 Bangunan Palm Grove No. 14, Jalan Glenmarie (Persiaran Kerjaya) Section U1 40150 Shah Alam Selangor.
2.	2.1 **SYNFLORIX VACCINE** [1 dose (0.5ml) contains: 1 mcg *S. Pneumonia* polysaccharide serotype 1[1] 1 mcg *S. Pneumonia* polysaccharide serotype 4[1] 1 mcg *S. Pneumonia* polysaccharide serotype 5[1] 1 mcg *S. Pneumonia* polysaccharide serotype 6B[1] 1 mcg *S. Pneumonia* polysaccharide serotype 7F[1] 1 mcg *S. Pneumonia* polysaccharide serotype 9V[1] 1 mcg *S. Pneumonia* polysaccharide serotype 14[1] 3 mcg *S. Pneumonia* polysaccharide serotype 18C[2] 3 mcg *S. Pneumonia* polysaccharide serotype 19F[3] 1 mcg *S. Pneumonia* polysaccharide serotype 23F[1] [1] conjugated to protein D (derived from NTHi) carrier protein [2] conjugated to tetanus toxoid carrier protein [3] conjugated to diphtheria toxoid carrier protein]	➢ Indication: Active vaccination of infants and children from the age of 6 weeks up to 5 years against disease caused by Streptococcus pneumoniae serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (including invasive disease, pneumonia and acute otitis media). ➢ Posology: Infants from 6 weeks to 6 months of age: Three-dose primary series with booster The primary vaccination schedule consists of three doses of 0.5ml with an interval of at least 1 month between doses. A booster dose is recommended at least 6 months after the last	**GLAXOSMITHKLINE PHARMACEUTICAL SDN BHD** Level 6, Quill 9, 112, Jalan Semangat No.8, Persiaran Tropicana, 47410 Petaling Jaya, Selangor.

		priming dose. Two-dose primary series with booster Alternatively, when Synflorix is given as part of a routine infant immunisation programme, a series consisting of three doses, each of 0.5ml may be given. The first dose may be administered from the age of 2 months, with a second dose 2 months later. A booster dose is recommended at least 6 months after the last primary dose. Preterm infants born after at least 27 weeks of gestational age The recommended immunisation series consists of four doses, each of 0.5ml. The primary infant series consists of three doses with the first dose usually given at 2 months of age and with an interval of at least 1 month between doses. A booster dose is recommended at least 6 months after the last primary dose. Previously unvaccinated older infants and children: - Infants aged 7-11 months: The vaccination schedule consists of two doses of 0.5ml with an interval of at least 1 month between doses. A third dose is recommended in the second year of life - Children aged 12-23 months: The vaccination schedule consists of two doses of 0.5ml which an interval of at least 2 months between doses. The need for a booster dose after this immunisation schedule has not been established. - Children aged 24 months – 5 years: The vaccination schedule consists of two doses of 0.5ml with an interval of at least 2 months between doses.	

3.	3.1 **BOTOX (BOTULINUM TOXIN TYPE A) IM INJECTION** [Clostridium Botulinum Toxin Type A 100 units/vial]	➢ For the treatment of urinary incontinence due to neurogenic detrusor overactivity (NDO) associated with Multiple Sclerosis or Spinal Cord Injury in adults who had an inadequate response or are intolerant of an anticholinergic medication.	**ALLERGAN MALAYSIA SDN. BHD.** No. 4A, Jalan 19/1 46300 Petaling Jaya, Selangor.
4.	4.1 **PEG-INTRON REDIPEN 50 MICROGRAMS** [Peginterferon alfa-2b] 4.2 **PEG-INTRON REDIPEN 80 MICROGRAMS** [Peginterferon alfa-2b] 4.3 **PEG-INTRON REDIPEN 100 MICROGRAMS** [Peginterferon alfa-2b] 4.4 **PEG-INTRON REDIPEN 120 MICROGRAMS** [Peginterferon alfa-2b] 4.5 **PEG-INTRON REDIPEN 150 MICROGRAMS** [Peginterferon alfa-2b]	➢ Peg-Intron* REDIPEN is indicated for the treatment of chronic hepatitis C and chronic hepatitis B. The optimal treatment for chronic hepatitis C is considered to be the administration of the combination of peginterferon alfa-2b with ribavirin. When Peg-Intron* REDIPEN is to be used in combination with ribarivin, please also refer to the ribavirin product information. This combination of peginterferon alfa-2b with ribavirin is indicated for the treatment of naïve, relapse and nonresponder patients with chronic hepatitis C with compensated liver disease, including those with histologic evidence of cirrhosis (Child-Pugh class A), and who are positive for serum HCV-RNA. This combination is also indicated for the treatment of patients with chronic hepatitis C who are co-infected with clinically stable HIV. Patients must be 18 years of age or older and have compensated liver disease.	**SCHERING-PLOUGH SDN BHD** T2-9, Jaya 33, No.3 (Lot 33), Jalan Semangat, Seksyen 13, 46100 Petaling Jaya, Selangor.
5.	5.1 **AVASTIN INJECTION 25 MG/ML** [Bevacizumab 25mg/ml]	➢ Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer 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. *FIGO : International Federation of Gynaecology and Obstetrics.	**ROCHE (M) SDN BHD** Level 56- 58, Vista Tower,The Intermark, 348, Jalan Tun Razak, 50400 Kuala Lumpur.

<table>
<tr>
<td>6.</td>
<td>6.1 XENETIX 300 – 50ML SOLN FOR INTRAVASCULAR INJ.
[Iobitridol 32.9g/50ml]

6.2 XENETIX 300 – 100ML SOLN FOR INTRAVASCULAR INJ.
[Iobitridol 65.81g/100ml]</td>
<td>

Indication:
This drug is an iodinated contrast agent with opacifying qualities for the purpose of radiological examination in adults and children undergoing:
- arthrography
- hysterosalpingography
Posology:

Recommended mean dosages for intracavitary routes:

<table>
<tr><th>Indications</th><th>Mean Volume (mL)</th><th>Comments</th></tr>
<tr><td>Arthrography</td><td>5 to 20</td><td>Volume adapted to the joint</td></tr>
<tr><td>Hysterosalpingography</td><td>5 to 20</td><td>Adapted to the uterine volume</td></tr>
</table>
</td>
<td>MEDI-DIAGNOSTIC SOLUTIONS (M) SDN. BHD.
No 17-1, Jalan PJU 1/3C
Sunwaymas Commercial Centre
47301 Petaling Jaya
Selangor</td>
</tr>
</table>