

Maklumat tambahan indikasi untuk upload pada laman web

Year 2013

Products Approved For Additional Indication (DCA 269 – 6 November 2013)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER																										
1.	<p>1.1 <b>PREVENAR 13 SUSPENSION FOR INJECTION</b> [1 dose (0.5ml) contains:</p> <table border="0"> <tr><td>Pneumococcal polysaccharide serotype 11</td><td>2.2µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 31</td><td>2.2µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 41</td><td>2.2µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 51</td><td>2.2µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 6A1</td><td>2.2µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 6B1</td><td>4.4µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 7F1</td><td>2.2µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 9V1</td><td>2.2µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 141</td><td>2.2µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 18C1</td><td>2.2µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 19A1</td><td>2.2µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 19F1</td><td>2.2µg</td></tr> <tr><td>Pneumococcal polysaccharide serotype 23F1</td><td>2.2µg</td></tr> </table> <p>1 Conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate (0.125mg aluminium)]</p>	Pneumococcal polysaccharide serotype 11	2.2µg	Pneumococcal polysaccharide serotype 31	2.2µg	Pneumococcal polysaccharide serotype 41	2.2µg	Pneumococcal polysaccharide serotype 51	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	<p>➤ Indication:</p> <p><i>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 (including invasive disease, pneumonia and acute otitis media) in infant, children and adolescents from 2 months to 17 years of age.</i></p> <p>➤ Posology:</p> <p><u>Method of administration</u></p> <p><i>The vaccine should be given by intramuscular injection. The preferred sites are the anterolateral aspect of the thigh (vastus lateralis muscle) in infants or the deltoid muscle of the upper arm in children and adults.</i></p> <p><u>Posology</u></p> <p><i>Data on the interchangeability of Prevenar (7 valent) or Prevenar 13 with other pneumococcal conjugate vaccines containing a protein carrier different from CRM197 are not available.</i></p> <p><i>It is recommended that infants who receive a first dose of Prevenar 13 complete the vaccination course with Prevenar 13.</i></p> <p><u>Infants aged 2-6 months</u> <i>Three-dose primary series</i></p>	<p><b>PFIZER (M) SDN BHD</b> Level 9-2, 10 &amp; 11 Wisma Averis, Tower 2 Avenue 5, Bangsar South No.8, Jalan Kerinchi 59200 Kuala Lumpur</p>
Pneumococcal polysaccharide serotype 11	2.2µg																												
Pneumococcal polysaccharide serotype 31	2.2µg																												
Pneumococcal polysaccharide serotype 41	2.2µg																												
Pneumococcal polysaccharide serotype 51	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																												

*The recommended immunisation series consists of four doses, each of 0.5 ml. 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. The first dose may be given as early as six weeks of age. The fourth (booster) dose is recommended between 12-15 months of age.*

*Two-dose primary series*

*Alternatively, when Prevenar 13 is given as part of a routine infant immunisation programme, a series consisting of three doses, each of 0.5 ml may be considered. The first dose may be given from the age of 2 months, with a second dose 2 months later. The third (booster) dose is recommended between 11-15 months of age.*

*Unvaccinated infants and children ≥ 7 months of age*

*Infants aged 7-11 months*

*Two doses, each of 0.5 ml, 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*

*Two doses, each of 0.5 ml, with an interval of at least 2 months between doses.*

*Children aged 2 years to 17 years*

*One single dose of 0.5 ml.*

*Prevenar 13 vaccine schedule for infants and children previously vaccinated with Prevenar (7 valent) (Streptococcus pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F)*

*Prevenar 13 contains the same 7 serotypes included in Prevenar (7 valent), using the same carrier protein CRM197.*

*Infants and children who have begun immunisation with Prevenar (7 valent) may*

		<p><i>switch to Prevenar 13 at any point in the schedule. In clinical trials, immunogenicity and safety profiles were comparable.</i></p> <p><i>Young Children (12-59 months) completely immunized with Prevenar (7 valent)</i>  <i>Young children who are considered completely immunised with Prevenar (7 valent) should receive one dose of 0.5 ml of Prevenar 13 to elicit immune responses to the 6 additional serotypes. This dose of Prevenar 13 should be administered at least 8 weeks after the final dose of Prevenar (7 valent).</i></p> <p><i>Children 5-17 years</i>  <i>Children 5 to 17 years of age may receive a single dose of Prevenar 13 if they have been previously vaccinated with one or more doses of Prevenar. This dose of Prevenar 13 should be administered at least 8 weeks after the final dose of Prevenar (7-valent).</i></p>	
2.	<p>2.1 <b>Kombiglyze XR Tablet 2.5/1000mg</b>  [Saxagliptin Hydrochloride anhydrous 2.79 mg (equivalent to saxagliptin 2.5 mg) and Metformin Hydrochloride 1000.50 mg (equivalent to Metformin 1000mg)]</p> <p>2.2 <b>Kombiglyze XR Tablet 5/1000mg</b>  [Saxagliptin Hydrochloride anhydrous 5.58 mg (equivalent to saxagliptin 5 mg) and Metformin Hydrochloride 1000.50 mg (equivalent to Metformin 1000mg)]</p> <p>2.3 <b>Kombiglyze XR Tablet 5/500mg</b>  [Saxagliptin Hydrochloride anhydrous 5.58 mg (equivalent to saxagliptin 5 mg) and Metformin Hydrochloride 502.50 mg (equivalent to Metformin 500mg)]</p>	<p>➤ Posology:</p> <p><i>Concomitant Use with an insulin Secretagogue (e.g., Sulphonylurea) or with Insulin</i>  <i>When Kombiglyze XR is used in combination with an insulin secretagogue (e.g., sulfonylurea) or with insulin, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycaemia.</i></p>	<p><b>ASTRAZENECA SDN. BHD.</b>  Level 12, Surian Tower,  1 Jalan PJU 7/3 Mutiara Damansara,  47810 Petaling Jaya,  Selangor.</p>

3. 3.1 **NUROFEN FOR CHILDREN**  
[Ibuprofen 100mg/5ml]

➤ Posology:

*Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms.*

*The daily dosage of Nurofen for Children is 20-30mg/kg bodyweight in divided doses. Using the spoon or syringe dosing device provided this can be achieved as follows:*

*Infants 3 – 6 months weighing more than 5kg: 2.5ml may be taken 3 times in 24 hours.*

*Infants 6 – 12 months: 2.5ml may be taken 3 to 4 times in 24 hours.*

*Children 1- 3 years: 5.0ml may be taken 3 times in 24 hours.*

*Children 4 – 6 years: 7.5ml may be taken 3 times in 24 hours.*

*Children 7 – 9 years: 10.0ml may be taken 3 times in 24 hours.*

*Children 10 – 12 years: 15.0ml may be taken 3 times in 24 hours.*

*The doses should be given approximately every 6-8 hours (or with a minimum of 4 hours between each dose if required)*

*Not suitable for children under 3 months of age unless advised by your doctor.*

*For post immunization pyrexia: 2.5ml dose following a further 2.5ml dose 6 hours later if necessary. No more than two 2.5ml doses in 24 hours. If the fever is not reduced, consult your doctor.*

*For oral administration.*

*For short term use only. If the child's (aged over 6 months) symptoms persist for more than 3 days, consult your doctor.*

**RECKITT BENCKISER (M) SDN. BHD.**

Level 5, Menara UAC  
No. 12, Jalan PJU 7/5  
Mutiar Damansara  
47800 Petaling Jaya,  
Selangor

*For children under 6 months, medical advice should be sought after 24 hours use (3 doses) if the symptoms persist.*