

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 396, 2 Mei 2024

Products approved for additional indication (DCA 396 – 2 May 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	<p>TRIMBOW (BECLOMETASON E DIPROPIONATE/ FORMOTEROL FUMARATE/ GLYCOPYRRONIUM BROMIDE 100/6/12.5 MICROGRAMS PRESSURISED INHALATION SOLUTION)</p> <p>[Beclomethasone Dipropionate 100mcg, Formoterol Fumarate Dihydrate 6mcg & Glycopyrronium Bromide 12.5mcg]</p>	<p>INDICATION :</p> <p>Asthma</p> <p>Maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and medium dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year.</p> <p>POSOLGY :</p> <p>Patients should be advised to take Trimbow every day even when asymptomatic.</p> <p>If symptom arise in the period between dose, an inhaled, short acting beta2-agonist should be used for immediate relief.</p> <p>Asthma</p> <p>When choosing the starting dose strength of Trimbow (87/5/9 micrograms), the patients' disease severity, their previous asthma therapy including the inhaled corticosteroid (ICS) dose as well as the patients' current control of asthma symptoms and risk of future exacerbation should be considered.</p> <p>Special populations</p> <p>Paediatric population</p> <p>Asthma</p> <p>The safety and efficacy of Trimbow in the paediatric population (under 18 years of age) have not yet been established. No data are available.</p>	<p>ORIENT EUROPHARMA (M) SDN. BHD. E-08, Garden Shoppe, One City, Jalan USJ 25/1C, 47650 Subang Jaya, Selangor.</p>

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2.	<p>SII PNEUMOSIL Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10- Valent) SUSPENSION FOR INJECTION (MULTIDOSE - 5 DOSE)</p> <p>SII PNEUMOSIL Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10- Valent) SUSPENSION FOR INJECTION (SINGLE DOSE - 1 DOSE)</p> <p>[Each dose of 0.5 ml contains the following: 2 mcg each of saccharide for serotypes 1, 5, 6A, 7F, 9V, 14, 19A, 19F, 23F; and 4 mcg of saccharide for serotype 6B]</p>	<p>POSOLGY:</p> <p><i>Vaccination Schedule</i></p> <p><i>SII PNEUMOSIL (10-valent) is to be administered as a three-dose primary series at 6, 10, and 14 weeks of age or 2, 3 and 4 months of age or 2, 4 and 6 months of age, with or without, depending on recommended dosing schedule, a booster dose at 9-10 or 12-15 months of age. The minimum interval between doses should be 4 weeks. If a booster dose is given, it should be at least 6 months after the last primary dose.</i></p> <p><i>Alternatively, SII PNEUMOSIL (10-valent) is given as a two-dose primary series with booster dose. The first dose may be administered from the age of 6 weeks, with a second dose at age of 14 weeks. The third (booster) dose is recommended between 9-18 months of age.</i></p> <table border="1" data-bbox="539 847 1697 1235"> <thead> <tr> <th colspan="5" data-bbox="539 847 1697 906"><i>Table 1: Vaccination Schedule for Infants and Toddlers</i></th> </tr> <tr> <th data-bbox="539 906 719 1010"><i>Dosage Schedules</i></th> <th data-bbox="719 906 969 1010"><i>Dose 1^{a, b}</i></th> <th data-bbox="969 906 1218 1010"><i>Dose 2^b</i></th> <th data-bbox="1218 906 1467 1010"><i>Dose 3^b</i></th> <th data-bbox="1467 906 1697 1010"><i>Dose 4^{c, d}</i></th> </tr> </thead> <tbody> <tr> <td data-bbox="539 1010 719 1114"><i>3p + 1</i></td> <td data-bbox="719 1010 969 1114"><i>6 weeks</i></td> <td data-bbox="969 1010 1218 1114"><i>10 weeks</i></td> <td data-bbox="1218 1010 1467 1114"><i>14 weeks</i></td> <td data-bbox="1467 1010 1697 1114"><i>9-10 months or 12-15 months</i></td> </tr> <tr> <td data-bbox="539 1114 719 1173"><i>3p + 0</i></td> <td data-bbox="719 1114 969 1173"><i>6 weeks</i></td> <td data-bbox="969 1114 1218 1173"><i>10 weeks</i></td> <td data-bbox="1218 1114 1467 1173"><i>14 weeks</i></td> <td data-bbox="1467 1114 1697 1173"><i>-</i></td> </tr> <tr> <td data-bbox="539 1173 719 1235"><i>2p + 1</i></td> <td data-bbox="719 1173 969 1235"><i>6 weeks</i></td> <td data-bbox="969 1173 1218 1235"><i>-</i></td> <td data-bbox="1218 1173 1467 1235"><i>14 weeks</i></td> <td data-bbox="1467 1173 1697 1235"><i>9-18 months</i></td> </tr> </tbody> </table> <p>^a <i>Dose 1 may be given as early as 6 weeks or at 2 months of age.</i></p> <p>^b <i>The recommended dosing interval is 4 to 8 weeks.</i></p> <p>^c <i>A booster (fourth) dose is recommended at least 6 weeks after the last primary dose and may be given from the age of 9 months onwards (preferably between 12 and 15</i></p>	<i>Table 1: Vaccination Schedule for Infants and Toddlers</i>					<i>Dosage Schedules</i>	<i>Dose 1^{a, b}</i>	<i>Dose 2^b</i>	<i>Dose 3^b</i>	<i>Dose 4^{c, d}</i>	<i>3p + 1</i>	<i>6 weeks</i>	<i>10 weeks</i>	<i>14 weeks</i>	<i>9-10 months or 12-15 months</i>	<i>3p + 0</i>	<i>6 weeks</i>	<i>10 weeks</i>	<i>14 weeks</i>	<i>-</i>	<i>2p + 1</i>	<i>6 weeks</i>	<i>-</i>	<i>14 weeks</i>	<i>9-18 months</i>	<p>PHARMANIAGA LIFESCIENCE SDN. BHD. Lot 7, Jalan PPU 3, Taman Perindustrian Puchong Utama, 47100 Puchong, Selangor.</p>
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		<p>months).</p> <p>^d A booster dose is recommended at the age of 9-18 months of age.</p> <p>For children who are beyond the age of routine infant schedule, the following SII PNEUMOSIL (10-valent) schedule is proposed:</p> <p>The catch-up schedule, for children 7 months through 2 years of age who have not received SII PNEUMOSIL (10-valent):</p> <table border="1" data-bbox="539 735 1682 1019"> <thead> <tr> <th colspan="2" data-bbox="539 735 1682 834">Table 2: Vaccination Schedule for Unvaccinated Children 7 Months of Age Through 2 Years of Age</th> </tr> <tr> <th data-bbox="539 834 1167 898">Age at first dose</th> <th data-bbox="1167 834 1682 898">Total number of 0.5 ml doses</th> </tr> </thead> <tbody> <tr> <td data-bbox="539 898 1167 962">7-11 months of age</td> <td data-bbox="1167 898 1682 962">3^a</td> </tr> <tr> <td data-bbox="539 962 1167 1019">12-24 months of age</td> <td data-bbox="1167 962 1682 1019">2^b</td> </tr> </tbody> </table> <p>^a The vaccination schedule consists of two primary doses of 0.5 ml with an interval of at least 1 month between doses. A booster (third) dose is recommended in the second year of life with an interval of at least 2 months after the last primary dose.</p> <p>^b The vaccination schedule consists of two doses of 0.5 ml with an interval of at least 2 months between doses.</p>	Table 2: Vaccination Schedule for Unvaccinated Children 7 Months of Age Through 2 Years of Age		Age at first dose	Total number of 0.5 ml doses	7-11 months of age	3 ^a	12-24 months of age	2 ^b	
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3.	<p>VARILRIX VACCINE</p> <p>Live Attenuated Varicella Virus (Oka Strain) <2000PFU/0.5ml</p>	<p>INDICATION:</p> <p>For post-exposure prophylaxis if administered to healthy, susceptible individuals exposed to varicella within 72 hours of contact (see “Warnings and Precautions” and “Pharmacodynamic effects”);</p> <p>POSODOLOGY:</p> <p>Post-exposure prophylaxis susceptible individuals exposed to varicella should receive one dose of Varilrix within 72 hours of contact.</p> <p>Individuals at high risk of severe varicella</p> <p>The same schedule described for healthy individuals should be applied for individuals at high risk of severe varicella (see “Pharmacodynamic Effects”).</p> <p>In these individuals, periodic measurement of varicella antibodies after vaccination may be indicated in order to identify those who may benefit from re-vaccination. In individuals at high risk of severe varicella additional doses of vaccine might be required. Under no circumstances should the interval between the doses be less than 4 weeks.</p>	<p>GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD. HZ.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.</p>