Maklumat tambahan indikasi

Tahun 2022

Products Approved For Additional Indication (DCA 369 – 10 Februari 2022)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Vaxigrip Tetra, Suspension for Injection in Pre-filled Syringe [Each dose of 0.5ml contains: Influenza virus (inactivated, split) of the following strains: ● A/Victoria/2570/2019 (H1N1)pdm09 - like strain (A/Victoria/2570/2019, IVR-215) 15mcg HA* ● A/Cambodia/e0826360/2020 (H3N2) - like strain (A/Tasmania/503/2020, IVR-221) 15 mcg HA* ● B/Washington/02/2019 - like strain (B/Washington/02/2019, wild type) 15 mcg HA* ● B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type) 15 mcg HA* * haemagglutinin]	**INDICATION :** Vaxigrip Tetra is indicated for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine for: - active immunisation of adults, **including pregnant women**, and children from 6 months of age. - **passive protection of infants less than 6 months of age and born to women vaccinated during pregnancy.** The use of Vaxigrip Tetra should be based on official recommendations. **POSOLOGY :** Based on clinical experience with the trivalent vaccine, annual revaccination with influenza vaccine is recommended given the duration of immunity provided by the vaccine and because circulating strains of influenza virus might change from year to year. Adults: one dose of 0.5 mL. <u>Paediatric population</u> • Children from 6 months to 17 years of age: one dose of 0.5 mL. For children less than 9 years of age who have not previously been vaccinated, a second dose of 0.5 mL should be given after an interval of at least 4 weeks. • **Infants less than 6 months of age: the safety and efficacy of VaxigripTetra administration (active immunisation) have not been established. No data are available.**	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** Unit TB-18-1, Level 18, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Regarding passive protection, one 0.5 mL dose administered to a pregnant woman may protect infants from birth to almost 6 months of age; however, not all infants may be protected. <u>Method of administration</u> The vaccine should be given by intramuscular or subcutaneous injection. The preferred site for intramuscular injection is the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 6 months through 35 months of age, or the deltoid muscle in children from 36 months of age and adults.	

<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>2.</td><td>Cosentyx 150mg/ml solution for injection in pre-filled pen

Cosentyx 150mg/ml solution for injection in pre-filled syringe

Fraizeron 150mg Powder for Solution for Injection

[Secukinumab 150mg]</td><td>INDICATION :

Cosentyx/Fraizeron is indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy.

POSOLOGY :

Plaque psoriasis:

Pediatric patients
The recommended dose is based on body weight (Table 1) and administered by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing (every 4 weeks). Each 75 mg dose is given as one subcutaneous injection of 75 mg. Each 150 mg dose is given as one subcutaneous injection of 150 mg. Each 300 mg dose is given as two subcutaneous injections of 150 mg.

Table 1 Recommended dose of secukinumab for pediatric plaque psoriasis
<table>
<tr><td>Body weight at time of dosing</td><td>Recommended Dose</td></tr>
<tr><td><25 kg</td><td>75 mg</td></tr>
<tr><td>25 to <50 kg</td><td>75 mg</td></tr>
<tr><td>≥50 kg</td><td>150 mg (*may be increased to 300 mg)</td></tr>
<tr><td colspan="2">*Some patients may derive additional benefit from the higher dose.</td></tr>
</table>

The 75mg solution for injection supporting the pediatric patients with body weight <50kg is not registered in this country.</td><td>NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.</td></tr>
</table>

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		The 150 mg solution for injection in pre-filled syringe & pen is not indicated for administration to pediatric patients with a weight <50 kg. The 150 mg powder for solution for injection presentation is appropriate for administration to this population.	