

Public Assessment Report
(Variation, New Indication)
INFLUVAC TETRA SH/NH

INFORMASI PRODUK

Nama obat	: Influvac Tetra SH Influvac Tetra NH
Bentuk sediaan	: Suspensi Injeksi
Zat aktif	: Influvac Tetra SH Tiap 0,5 mL mengandung: a. A/Victoria/2570/2019 (H1N1) pdm09 – like virus (A/Victoria/2570/2019, IVR-215), 15 mcg b. A/Hongkong/2671/2019 (H3N2) – like virus (A/Hongkong/2671/2019, IVR-208), 15 mcg c. B/Phuket/3073/2013-like virus (B/Phuket/3073/2013, wild type), 15 mcg d. B/Washington/02/2019-like virus (B/Washington/02/2019, wild type), 15 mcg Influvac Tetra NH Tiap 0,5 mL mengandung: a. A/Victoria/2570/2019 (H1N1) pdm09-like virus (A/Victoria/2570/2019, IVR-215), 15 mcg b. A/Cambodia/e0826360/2020 (H3N2)-like virus (A/Cambodia/0826360/2020, IVR-224), 15 mcg c. B/Washington/02/2019-like virus (B/Washington/02/2019, wild type), 15 mcg d. B/phuket/3073/2013-like virus (B/Phuket/3073/2013, wild type) 15 mcg
Kemasan	: Dus, 1 pre-filled syringe @ 0,5 mL
Pendaftar	: PT. Abbot Indonesia
Produsen	: Abbott Biologicals B.V., Netherlands
Kategori Registrasi	: Penambahan indikasi dan posologi baru
Indikasi yang diajukan:	<i>Prophylaxis of influenza, especially those who run an increased risk of associated complications.</i> <i>Influvac® Tetra is indicated in adults and children from 6 months of age.</i> <i>The use of Influvac® Tetra should be based on official recommendations.</i> <i>Vaccination is particularly recommended for the following categories of patients:</i> <i>- Persons aged ≥ 65 years, regardless their health condition.</i> <i>- Adults and children from 6 months of age with chronic disorders of the pulmonary or cardiovascular systems, including asthma.</i> <i>- Adults and children from 6 months of age with chronic metabolic diseases such as diabetes mellitus.</i> <i>- Adults and children from 6 months of age with chronic renal dysfunction.</i> <i>- Adults and children from 6 months of age with immunodeficiencies due to disease or immunosuppressant medication (e.g., cytostatics or corticosteroids) or radiotherapy.</i> <i>- Children from 6 months of age who receive long-term acetylsalicylic acid containing medication, and might therefore be at risk for developing Reye's syndrome following an influenza infection.</i>
Posologi yang diajukan	: <i>Adults: 0.5 ml.</i> <i>Paediatric patients</i> <i>Children from 6 months to 17 years of age: 0.5 mL.</i> <i>Children less than 9 years of age, who have not previously been vaccinated with a seasonal influenza vaccine: a second dose of 0.5 mL should be given after an interval of at least 4 weeks.</i> <i>Infants less than 6 months of age: the safety and efficacy of Influvac ® Tetra have not been established.</i>

PENGANTAR

Influvac Tetra adalah vaksin influenza yang dikembangkan oleh Abbott Biologicals B.V., India dengan platform *inactivated virus*. Vaksin ini sebelumnya sudah disetujui untuk dewasa dan anak mulai usia 3 tahun. Registrasi ini adalah pengajuan indikasi baru pada bayi mulai usia 6 bulan.

ASPEK KHASIAT DAN KEAMANAN
Studi Klinik

Diserahkan laporan studi klinik INFQ3003 *A Phase III, Observer-Blind, Randomized, Non-influenza Vaccine Comparator-Controlled, Parallel-Group, Multi-Country Study in Children Aged 6–35 Months to Assess the Safety and Efficacy of Abbott’s Candidate Quadrivalent Influenza Vaccine* yang merupakan studi klinik fase 3 dengan desain *observer-blind, randomized, multi-country* yang bertujuan untuk menilai efikasi vaksin pada anak usia 6-35 bulan (N=2000).

Hasil evaluasi terhadap studi:

Berdasarkan hasil studi INFQ3003 pada subjek usia 6-35 bulan yang belum pernah mendapatkan vaksinasi influenza / riwayat influenza vaccine, pemberian Quadrivalent Influenza Vaccine (QIV) 2 dosis interval 28 – 33 hari menunjukkan:

- a. Efikasi yang baik terhadap any circulating influenza strain sebesar 0,54 maupun antigenically matching circulating influenza strain sebesar 0,68 dengan serokonversi untuk strain A (H3N2 86,2% - 92,5% dan H1N1 69,8% - 76%) dan strain B (B Vic 26,5% - 65,2% dan B yam 16,9% - 56%).
- b. Profil keamanan yang dapat ditoleransi, tidak ada Adverse Events (AEs) jenis baru yang dilaporkan.

KEPUTUSAN

Mempertimbangkan data khasiat dan keamanan tersebut di atas, diputuskan registrasi Influvac Tetra SH dan Influvac Tetra NH suspensi injeksi untuk usia 6 bulan keatas dapat diterima sesuai dengan indikasi dan posologi yang diajukan.

Indication

Prophylaxis of influenza, especially those who run an increased risk of associated complications. Influvac® Tetra is indicated in adults and children from 6 months of age. The use of Influvac® Tetra should be based on official recommendations. Vaccination is particularly recommended for the following categories of patients:

- *Persons aged ≥ 65 years, regardless their health condition.*
- *Adults and children from 6 months of age with chronic disorders of the pulmonary or cardiovascular systems, including asthma.*
- *Adults and children from 6 months of age with chronic metabolic diseases such as diabetes mellitus.*
- *Adults and children from 6 months of age with chronic renal dysfunction.*
- *Adults and children from 6 months of age with immunodeficiencies due to disease or immunosuppressant medication (e.g., cytostatics or corticosteroids) or radiotherapy.*
- *Children from 6 months of age who receive long-term acetylsalicylic acid containing medication, and might therefore be at risk for developing Reye’s syndrome following an influenza infection.*

Dosage and Administration

*Adults: 0.5 ml.
Pediatric patients
Children from 6 months to 17 years of age: 0.5 mL.
Children less than 9 years of age, who have not previously been vaccinated with a seasonal influenza vaccine: 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 Influvac ® Tetra have not been established*

