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רופא/ה, רוקח/ת נכבד/ה,

אוגוסט 2021

INFLUVAC® TETRA

אינפלובאק טטרה

SEASON 2021/2022 עונה

Quadrivalent Influenza Vaccine
Suspension for Injection

אבוט מעבדות רפואית בע"מ מתכבדת להודיע על זמינות החיסון לעונה 2021/2022 ואישור משרד הבריאות להרחבת ההתוויה לילדים מגיל 3 עד 17 שנים.

הרכב התכשיר עודכן בזני השפעת לעונה 2021/2022:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (inactivated) (haemagglutinin and neuraminidase) of the following strains*:

~~- A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like strain (A/Guangdong-Maonan/SWL1536/2019, CNIC-1909)~~ - A/Victoria/2570/2019 (H1N1)pdm09-like strain (A/Victoria/2570/2019, IVR-215)	15 micrograms HA **
~~- A/Hong Kong/2671/2019 (H3N2)-like strain (A/Hong Kong/2671/2019, IVR-208)~~ - A/Cambodia/e0826360/2020 (H3N2)-like strain (A/Cambodia/e0826360/2020, IVR-224)	15 micrograms HA **
- B/Washington/02/2019-like strain (B/Washington/02/2019, wild type)	15 micrograms HA **
-B/Phuket/3073/2013-like strain (B/Phuket/3073/2013, wild type)	15 micrograms HA **
	per 0.5 ml dose
* propagated in fertilised hens' eggs from healthy chicken flocks ** haemagglutinin.	

This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the ~~2020/2021~~ 2021/2022 season.
[…]

הרחבת גיל המטופלים בהתוויה ומשטר המינון עודכנו באופן הבא בעלון:

4.1 Therapeutic indications

Prophylaxis of influenza, especially those who run an increased risk of associated complications.
Influvac Tetra is indicated in adults ~~(18 years of age and older)~~ and children from 3 years of age.
The use of Influvac Tetra should be based on official recommendations

4.2 Posology and method of administration

Posology
Adults: 0.5 ml.
Paediatric population
~~Children and adolescents: the safety and efficacy of Influvac Tetra in children and adolescents below 18 years of age have not been established.~~
Children from 3 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.
Children less than 3 years of age: the safety and efficacy of Influvac Tetra in children have not been established.

Method of Administration
Immunisation should be carried out by intramuscular or deep subcutaneous injection. The preferred site for intramuscular injection is the deltoid muscle in children from 36 months of age and adults.

4.8 Undesirable effects

a. Summary of the safety profile
~~Safety data regarding the use of Influvac Tetra are based on a clinical study in healthy adults 18 years of age and older: Influvac Tetra was administered to 1535 subjects (768 adults aged 18 – 60 years of age and 767 elderly aged 61 years or older) and trivalent influenza vaccine Influvac to 442 subjects (222 adults aged 18 – 60 years of age and 220 elderly aged 61 years or older).~~
The safety of Influvac Tetra was assessed in two clinical trials in which healthy adults 18 years of age and older, and healthy children 3 to 17 years of age were administered Influvac Tetra or trivalent influenza vaccine Influvac. Children from 3 to 8 years of age received one or two doses of Influvac Tetra depending on their influenza vaccination history.

~~The~~Most reactions usually occurred within the first 3 days following vaccination and resolved spontaneously within 1 to 3 days after onset. The intensity of these reactions was generally mild.
In all age groups, the most frequently reported local adverse reaction after vaccination observed in the clinical ~~study~~studies for Influvac Tetra was vaccination site pain ~~(16.3%).~~.
The most frequently reported general adverse reactions after vaccination observed in the clinical ~~study~~studies for Influvac Tetra in adults and children from 6 to 17 years of age were fatigue ~~(11.2%)~~ and headache ~~(10.3%).~~, and for children from 3 to 5 years of age drowsiness, irritability and loss of appetite.

Similar rates of solicited adverse reactions were observed in recipients of Influvac Tetra and trivalent influenza vaccine Influvac.

[…]

Paediatric population

Children (3 to 17 years of age) Adverse Reactions Reported with *Influvac Tetra*/Influvac				
MedDRA System Organ Class	**Very common ≥ 1/10**	**Common ≥ 1/100 to < 1/10**	**Uncommon ≥ 1/1,000 to < 1/100**	**Not Known[a] (cannot be estimated from the available data)**
Blood and lymphatic system				Transient thrombocytopenia, transient lymphadenopathy
Immune system disorders				Allergic reactions, in rare cases leading to shock, angioedema
Nervous system disorders	Headache[d] Drowsiness[b]			Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome
Vascular disorders				Vasculitis associated in very rare cases with transient renal involvement

Skin and subcutaneous tissue disorders		Sweating[c]		Generalised skin reactions including pruritus, urticaria or non-specific rash
Metabolism and nutrition disorders	Appetite loss[b]			
Gastrointestinal disorders	Gastrointestinal symptoms[d]	Diarrhoea[b], vomiting[b]		
Psychiatric disorders	Irritability[b]			
Musculoskeletal and connective tissue disorders	Myalgia[d]	Arthralgia[d]		
General disorders and administration site conditions	Fatigue[d], malaise[d] Local reactions: pain[c], redness[c], swelling[c], induration[c]	Fever[c], shivering[d] Local reaction: ecchymosis[c]		

[a] Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure
[b] Reported as a solicited symptom in children 3 to 5 years of age
[c] Reported as a solicited symptom in children 3 to 17 years of age
[d] Reported as a solicited symptom in children 6 to 17 years of age

[…]

5.1. Pharmacodynamic properties

[…]

Pharmacodynamic effects:
Immunogenicity of Influvac Tetra compared to trivalent Influvac:
~~A clinical study~~Clinical studies performed in adults of 18 years of age and older (INFQ3001) and children of 3 to 17 years of age (INFQ3002) assessed the safety and immunogenicity of Influvac Tetra and its non-inferiority to trivalent influenza vaccine Influvac for the postvaccination HI Geometric mean antibody titer (GMT~~) at Day 22.~~).
In ~~the study~~both studies the immune response elicited by Influvac Tetra against the three strains in common was non-inferior to trivalent influenza vaccine Influvac. Influvac Tetra elicited a superior immune response against the additional B strain included in Influvac Tetra compared to trivalent influenza vaccine Influvac.
[…]
Paediatric population
Children 3 – 17 years of age:
In clinical study INFQ3002, 402 children of 3 to 17 years of age received one or two doses of Influvac Tetra and 798 children received one or two doses of trivalent Influvac based on their influenza vaccination history.
Table: Post-vaccination GMT

Children 3 - 17 years of age	Influvac Tetra N=396	Influvac[1] N=389	Influvac[2] N=399
	GMT (95% confidence interval)		
A/H1N1	546.2 (487.1 , 612.6)	605.6 (536.3 , 83.8)	633.1 (562.8 , 712.2)
A/H3N2	1161.5 (1035.8 , 1302.5)	1075.4 (947.7 , 1220.3)	1306.4 (1162.5 , 1468.1)
B (Yamagata)[3]	280.8 (246.2 , 320.1)	269.0 (232.8 , 310.7)	38.3 (31.9 , 46.1)
B (Victoria)[4]	306.7 (266.0 , 353.6)	104.5 (86.8 , 125.8)	361.4 (311.0 , 420.0)

N= number of subjects included in efficacy analysis
[1]containing A/H1N1, A/H3N2 and B (Yamagata lineage)

[2]containing A/H1N1, A/H3N2 and B (Victoria lineage)
[3]recommended B strain by WHO for the season 2016-2017 NH for trivalent vaccines
[4]additional recommended B strain by WHO for season 2016-2017 NH for quadrivalent vaccines
The European Medicines Agency has deferred the obligation to submit the results of studies with Influvac Tetra in one or more subsets of the paediatric population.

בהודעה זו מפורטים רק השינויים המהותיים. למידע נוסף אודות התכשיר יש לעיין בעלון לרופא המעודכן.

העלון נשלח למשרד הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פניה לבעל הרישום, אבוט מעבדות רפואיות בע"מ, קריית עתידים, ת.ד 58099 ת"א או בטלפון 03-7691000

בברכה,

לירן מימון
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