



27.08.2020

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

הנדון: VAXIGRIP TETRA - וקסיגריפ טטרא
Suspension for Injection

חברת מדיצי' מדיקל בע"מ מבקשת להודיע על עדכון העלון לרופא של חיסון השפעת העונתית Vaxigrip Tetra / וקסיגריפ טטרא. עדכון העלון כולל זנים חדשים עבור חורף 2020/2021 ותיקון Tyco לפי המפורט מטה.

Indication: Vaxigrip Tetra is indicated for active immunisation of adults and children from 6 months of age and older 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.

The use of Vaxigrip Tetra should be based on official recommendations

מקרא לסימון העדכונים: טקסט חדש – כחול, מחיקה - אדום עם קו חוצה, שינוי מיקום – טקסט ירוק עם שני קווים מתחתיו

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus (inactivated, split) of the following strains*:

A/Guangdong-Maonan/SWL1536/2019 ~~Brisbane/02/2018~~ (H1N1)pdm09 - like strain

..... ~~(A/Brisbane/02/2018, IVR-190)~~ 15 micrograms HA**

A/Hong Kong/2671/2019 ~~A/Kansas/14/2017~~ (H3N2) - like strain (A/Hong Kong/2671/2019, IVR-

208)..... ~~Kansas/14/2017, NYMC X-327)~~ 15 micrograms HA**

B/Washington/02/2019 - ~~Colorado/06/2017~~-like strain (B/Washington/02/2019, wild type).....

~~Maryland/15/2016, NYMC BX-69A)~~..... 15 micrograms HA**

B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type)..... 15 micrograms HA**

Per one 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks

** haemagglutinin

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the ~~2019/2020/2021~~ season.

[...]

4.8. Undesirable effects

[...]

Paediatric population

The safety profile presented below is based on data from 429 children from 9 to 17 years of age who received one dose of Vaxigrip Tetra and from 884 children from 3 to 8 years of age who received one or two doses of Vaxigrip Tetra depending on their influenza vaccination history.

~~The safety profile presented below is based on data from 1,614 children from 6 to 35 months who received two doses of Vaxigrip Tetra.~~

ADVERSE REACTIONS	FREQUENCY
Blood and lymphatic system disorders	
Thrombocytopaenia ⁽¹⁾	Uncommon
Psychiatric disorders	
Moaning ⁽²⁾ , restlessness ⁽²⁾	Uncommon
Nervous system disorders	
Headache	Very common
Dizziness ⁽²⁾	Uncommon
Gastrointestinal disorders	
Diarrhoea, vomiting ⁽²⁾ , abdominal pain upper ⁽²⁾	Uncommon
Musculoskeletal and connective tissue disorders	
Myalgia	Very common
Arthralgia ⁽²⁾	Uncommon
General Disorders and administration site conditions	
Malaise, shivering ⁽³⁾	Very common



Injection site pain, injection site swelling, injection site erythema ⁽³⁾ , injection site induration ⁽³⁾	
Fever Injection site ecchymosis	Common
Fatigue ⁽²⁾ Injection site warmth ⁽²⁾ , injection site pruritus ⁽⁴⁾	Uncommon

⁽¹⁾ Reported in one child of 3 years of age

⁽²⁾ Reported in children from 3 to 8 years of age

⁽³⁾ Common in children from 9 to 17 years of age

⁽⁴⁾ Reported in children from 9 to 17 years of age

The safety profile presented below is based on data from 1,614 children from 6 to 35 months who received two doses of Vaxigrip Tetra.

ADVERSE REACTIONS	FREQUENCY
Immune System Disorders	
Hypersensitivity	Uncommon
Allergic reactions such as pruritus generalised, rash papular	Rare
Nervous System Disorders	
Headache ⁽¹⁾	Very common
Gastrointestinal Disorders	
Vomiting ⁽²⁾	Very common
Diarrhoea	Uncommon
Musculoskeletal and Connective Tissue Disorders	
Myalgia ⁽³⁾	Very common
General Disorders and Administration Site Conditions	
Irritability ⁽⁴⁾ , appetite lost ⁽⁴⁾ , crying abnormal ⁽⁵⁾ , malaise ⁽³⁾ , fever, drowsiness ⁽⁵⁾ , injection site pain/tenderness, injection site erythema	Very common
Shivering ⁽¹⁾ Injection site induration, injection site swelling, injection site ecchymosis	Common
Injection site rash, injection site pruritus, influenza like illness	Rare

⁽¹⁾ Reported in children ≥ 24 months of age

⁽²⁾ Uncommon in children ≥ 24 months of age

⁽³⁾ Rare in children < 24 months of age

⁽⁴⁾ Rare in children ≥ 24 months of age

⁽⁵⁾ Reported in children < 24 months of age

In children from 6 months to 8 years of age, the safety profile of Vaxigrip Tetra was similar after the first and the second injections with a trend of lower incidence of adverse reactions after the second injection compared to the first one in children from 6 to 35 months.

[...]

למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

<https://data.health.gov.il/drugs/index.html#!/medDetails/160%2019%2035153%2000> וניתן לקבלו מודפס על ידי

פניה לחברת מדיצי' מדיקל בע"מ, רח' המחשב 3 נתניה, בטלפון 09-7446170.

בברכה,

האלה ביאדסה - רוקחת ממונה