נובמבר 2019

הנדון: VAXIGRIP TETRA וקסיגריפ טטרא

Suspension for Injection

רופא/ ה נכבד/ ה

רוקח/ת נכבד/ה,

חברת מדיצ'י מדיקל בע"מ מבקשת להודיע על עדכון העלון לרופא של חיסון השפעת העונתית Vaxigrip Tetra / וקסיגריפ טטרא. עדכון העלון כולל גם עדכון הזנים עבור חורף 2019-2020.

חומרים פעילים:

A/Brisbane/02/2018 (H1N1)pdm09 - like strain (A/Brisbane/02/2018, IVR-190) ……..15 µg HA**

A/Kansas/14/2017 (H3N2) - like strain (A/Kansas/14/2017, NYMC X-327) …… 15 µg HA**
B/Colorado/06/2017-like strain (B/Maryland/15/2016, NYMC BX-69A)……15 µg HA**
B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type)……..15 µg HA**
Per one 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

התוויה:

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

בהודעה זו מצוינים השינויים שבוצעו לעלון

מקרא לעדכונים המסומנים:
תוספת –כחול
מחיקה- ~~אדום עם קו מחיקה~~
החמרה – בצהוב

להלן העדכונים המהותיים שנעשו בעלון לרופא:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

A/Brisbane/02/2018 (H1N1)pdm09 - like strain (A/Brisbane/02/2018, IVR-190)~~A/Michigan/45/2015 (H1N1)pdm09 - like strain (A/Michigan/45/200215, NYMC X-275)~~ ….15 micrograms HA**
A/Kansas/14/2017 (H3N2) - like strain (A/Kansas/14/2017, NYMC X-327)~~A/Singapore/INFIMH-16-0019/2016 (H3N2) - like strain (A/Singapore/INFIMH-16-0019/2016,IVR-186)~~ … 15 micrograms HA**
B/Colorado/06/2017-like strain (B/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 ~~2018/2019~~2019/2020 season.

[……]

4.6. Fertility, pregnancy and lactation

Pregnancy

Pregnant women are at high risk of influenza complications, including premature labour and delivery, hospitalization, and death: pregnant women should receive an influenza vaccine.

Inactivated influenza vaccines can be used in all stages of pregnancy.

Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of inactivated influenza vaccines do not indicate any adverse foetal and maternal outcomes attributable to the vaccine.

~~There are no data on the use of Vaxigrip Tetra in pregnant women.~~

Data from four clinical studies with the trivalent inactivated influenza vaccine (Inactivated Influenza Vaccine (Split Virion) BP thiomersal-free formulation) administered in pregnant women during the second or third trimester (more than 5,000 exposed pregnancies followed up to approximately 6 months post-partum) did not indicate any adverse maternal outcomes attributable to the vaccine.

In clinical studies conducted in South Africa and Nepal, there were no significant differences between the Inactivated Influenza Vaccine BP and placebo groups with regards to maternal outcomes (including premature birth).

In a study conducted in Mali, there were no significant differences between the Inactivated Influenza Vaccine (Split Virion) BP and control vaccine (quadrivalent meningococcal conjugate vaccine) groups with regards to prematurity rate, stillbirth rate and low birth weight/small for gestational age rate.

For additional information, see Sections 4.8 and 5.1.

One animal study with Vaxigrip Tetra did not indicate direct or indirect harmful effects with respect to pregnancy, embryo-foetal development or early post-natal development.

[……]

.d. Other special populations

The safety profile of VaxigripTetra observed in limited number of subjects with co-morbidities enrolled in the clinical studies does not differ from the one observed in the overall population. In addition, studies conducted with Vaxigrip in renal transplant patients, and asthmatic patients showed no major differences in terms of safety profile of Vaxigrip in these populations.

In clinical studies conducted in pregnant women in South Africa and Mali with Vaxigrip tetra (see Sections 4.6 and 5.1), frequencies of local and systemic solicited reactions reported within 7 days following administration of the vaccine, were consistent with those reported for the adult population during clinical studies conducted with Vaxigrip tetra. In the South Africa study, local reactions were more frequent in the Vaxigrip tetra group than in the placebo group in both HIV-negative and HIV-positive cohorts. There were no other significant differences in solicited reactions between Vaxigrip tetra Vaccine and placebo groups in both cohorts.

[……]

These immunogenicity data provide supportive information in addition to vaccine efficacy data available in this population (see Efficacy of Vaxigrip Tetra).

Pregnant Women

Necessary influenza vaccination during the first trimester should not be postponed (see section 4.6).

In randomized, controlled phase IV clinical studies conducted in Mali, Nepal and South Africa, approximately 5,000 pregnant women received Inactivated Influenza Vaccine (Split Virion) BP (trivalent influenza thiomersal-free vaccine) and approximately 5,000 pregnant women received placebo or control vaccine (quadrivalent meningococcal conjugate vaccine) during the second or third trimester of pregnancy. Vaccine efficacy against laboratory confirmed influenza in pregnant women was evaluated as a secondary endpoint in all three studies.

The studies conducted in Mali and South Africa demonstrated the efficacy of Inactivated Influenza

Vaccine (Split Virion) BP for the prevention of influenza in pregnant women following vaccination during these trimesters of pregnancy (see table 4). In the study conducted in Nepal, the efficacy of Inactivated Influenza Vaccine (Split Virion) BP for the prevention of influenza in pregnant women following vaccination during these trimesters of pregnancy was not demonstrated.

Table 4: Influenza Attack Rates and Inactivated Influenza Vaccine (Split Virion) BP Efficacy against Laboratory-confirmed influenza in pregnant women

	Influenza Attack Rate (Any influenza A or B type) % (n/N)		**Inactivated Influenza Vaccine (Split Virion) BP Efficacy % (95% CI)**
	TIV	**Control***	
Mali	2.4 (45/1,866)	3.8 (71/1,869)	37.3 (7.6 to 57.8)
	TIV	**Placebo**	
Nepal	4.1 (74/1,820)	5.8 (105/1,826)	30.0 (5 to 48)
South Africa	1.9 (19/1,026)	3.6 (37/1,023)	48.8 (11.6 to 70.4)

* Meningococcal vaccine
N: Number of pregnant women included in analysis
n: number of subjects with laboratory confirmed infuenza CI: Confidence Interval

למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון נשלח לרופא 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 מדיצ'י מדיקל בע"מ רח' המחשב 3 נתניה בטלפון 09-7446170

בברכה,

האלה ביאדסה

רוקחת ממונה