

13.10.2021

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 הרחבת התוויה .

Indication: Vaxigrip Tetra (Quadrivalent Influenza Vaccine (split virion, inactivated) 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 and older,
- passive protection of infant(s) from birth to less than 6 months of age following vaccination of pregnant women (see Sections 4.4, 4.6 and 5.1).

The use of Quadrivalent Influenza Vaccine (split virion, inactivated) should be based on official recommendations.

מקרא לסימון העדכונים: טקסט חדש – אדום, מחיקה – אדום עם קו חוצה.

[...]

4. Clinical particulars

4.1 Therapeutic indications

Vaxigrip Tetra (Quadrivalent Influenza Vaccine (split virion, inactivated)) is indicated ~~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- for:

- active immunisation of adults, including pregnant women, and children from 6 months of age and older,

- passive protection of infant(s) from birth to less than 6 months of age following vaccination of pregnant women (see Sections 4.4, 4.6 and 5.1).

The use of ~~Vaxigrip Tetra~~Quadrivalent Influenza Vaccine (split virion, inactivated) should be based on official recommendations.

4.2 Posology and method of administration

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.

Paediatric population

- 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 Vaxigrip Tetra administration (active immunisation) have not been established. No data are available.

Regarding passive protection: one 0.5mL dose given to pregnant women may protect infants from birth to less than 6 months of age; however, not all these infants will be protected (see section 5.1).

[...]

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

Vaxigrip Tetra should under no circumstances be administered intravascularly.

As with other vaccines administered intramuscularly, the vaccine should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.

Vaxigrip Tetra is intended to provide protection against those strains of influenza virus from which the vaccine is prepared.

As with any vaccine, vaccination with Vaxigrip Tetra may not protect all vaccinees.

Regarding passive protection, not all infants less than 6 months of age born to women vaccinated during pregnancy will be protected (see section 5.1).

[...]

קיימים עדכונים נוספים, **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,

ירון חסיד - רוקח ממונה