אוקטובר 2025

הנדון: <u>פריוריקס טטרה / Priorix Tetra</u>
<u>Powder and solvent for solution for injection</u>

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לרופא של התכשיר פריוריקס טטרה / Priorix Tetra.

בהודעה זו כלולים השינויים המהותיים בעלון לרופא. בעלון ישנם שינויים נוספים.

מרכיבים פעילים וחוזקם:

- LIVE ATTENUATED MUMPS VIRUS	NLT 10 $^{3.7}$CCID$_{50}$
- LIVE ATTENUATED RUBELLA VIRUS	NLT 10 $^{3.0}$CCID$_{50}$
- LIVE ATTENUATED MEASLES VIRUS	NLT 10 $^{3.0}$CCID$_{50}$
- VARICELLA VIRUS, LIVE ATTENUATED	NLT 10 $^{3.3}$ PFU

ההתוויה המאושרת ע"י משרד הבריאות:

Priorix-Tetra is indicated for active immunisation against measles, mumps, rubella and varicella in children from the age of 12 months up and including 12 years of age.

מקרא לעדכונים המסומנים:

- מידע שהוסר – מסומן בקו אדום חוצה ~~XXX~~
- תוספת – כתב כחול
- תוספת החמרה - מסומן בצהוב מרקר

שינוי מיקום טקסט- כתב ירוק

<u>עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:</u>

4.1 Therapeutic indications

Priorix Tetra is indicated for active immunisation against measles, mumps, rubella and varicella in children from the age of 12 months up and including 12 years of age.

~~Use in infants aged 9-11 months could be considered under special circumstances. See section 4.2.~~

Note: The use of Priorix Tetra should be based on official recommendations.

4.2 Posology and method of administration

<u>Posology</u>
Children from 12 months up to 12 years
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~~*Children from 9 to 11 months*~~
~~In case an epidemiological situation requires vaccinating infants less than 12 months of age, the first dose of Priorix Tetra can be given as from 9 months of age. A second dose of Priorix Tetra should be given three months after the first dose (see section 5.1).~~

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4.3 Contraindications

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Current or recent immunosuppressive therapy (including high doses of corticosteroids). Priorix Tetra is not contraindicated in individuals who are receiving topical or low-dose parenteral corticosteroids (e.g. for asthma prophylaxis or replacement therapy) (see section 4.4).

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4.4 Special warnings and precautions for use

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Immunocompromised patients
Vaccination may be considered in patients with selected immune deficiencies where the benefits outweigh the risks (e.g. asymptomatic HIV subjects, IgG subclass deficiencies, congenital neutropenia, chronic granulomatous disease, and complement deficiency diseases).

Immunocompromised patients who have no contraindication for this vaccination (see section 4.3) may not respond as well as immunocompetent subjects, therefore some of these patients may acquire measles, mumps, rubella or varicella in case of contact, despite appropriate vaccine administration. These patients should be monitored carefully for signs of measles, parotitis, rubella and varicella.
Due to the potential risk of decreased vaccine response and/or disseminated diseases, consideration should be given to the time interval between Priorix Tetra vaccination and immunosuppressive therapy (see section 4.3).
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Encephalitis

Encephalitis has been reported during post-marketing use of live attenuated measles, mumps, rubella and varicella vaccines. In a few cases fatal outcomes have been observed, especially in patients who were immunocompromised (see section 4.3). Vaccinees/parents should be instructed to seek prompt medical attention if they/their child experience, after vaccination, symptoms suggestive of encephalitis such as loss or reduced levels of consciousness, convulsions or ataxia accompanied by fever and headache.

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4.6 Fertility, pregnancy and lactation

Fertility
Priorix Tetra has not been evaluated in fertility studies.

Pregnancy
Pregnant women should not be vaccinated with Priorix-Tetra.

Studies have not been conducted with Priorix Tetra in pregnant women.

In a review of more than 3 500 susceptible women who were unknowingly in early stages of pregnancy when vaccinated with a rubella-containing vaccine, no cases of congenital rubella syndrome were reported. Subsequent post-marketing surveillance identified congenital rubella syndrome associated with a rubella vaccine strain (Wistar RA 27/3) following inadvertent vaccination of a pregnant woman with a measles, mumps and rubella vaccine

~~However, f~~Foetal damage has not been documented when measles, mumps~~, rubella~~ or varicella vaccines have been given to pregnant women.

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4.8 Undesirable effects

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Post-marketing surveillance data

The following additional adverse reactions have been identified in rare occasions during post-marketing surveillance. Because they are reported voluntarily from a population of unknown size, a true estimate of frequency cannot be provided.

System Organ Class	Adverse reactions
Infections and infestations	meningitis, herpes zoster*, measles-like syndrome, mumps-like syndrome (including orchitis, epididymitis and parotitis)
Blood and lymphatic system disorders	thrombocytopenia, thrombocytopenic purpura
Immune system disorders	allergic reactions (including anaphylactic and anaphylactoid reactions)
Nervous system disorders	encephalitis*+, cerebellitis, cerebrovascular accident, Guillain Barré syndrome, transverse myelitis, peripheral neuritis, cerebellitis like symptoms (including transient gait disturbance and transient ataxia)
Vascular disorders	vasculitis
Skin and subcutaneous tissue disorders	erythema multiforme, varicella-like rash
Musculoskeletal and connective tissue disorders	arthralgia, arthritis

* ~~This~~ These selected adverse ~~drug~~ reactions reported after vaccination ~~is~~ are also a consequence of wild-type varicella infection. There is no indication of an increased risk of these adverse reactions~~herpes zoster occurrence~~ following vaccination compared with wild-type disease.
+see description of selected adverse reactions

Description of selected adverse reactions
Encephalitis has been observed following vaccination with live attenuated measles, mumps, rubella and varicella vaccines. Fatal outcome was reported in a few cases, especially in immunocompromised people (see section 4.4).

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5.1 Pharmacodynamic properties

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~~*Immune response in children aged 9 to 10 months*~~
~~A clinical trial conducted in Asia (Singapore) enrolled 300 healthy children 9 to 10 months of age at the time of first vaccine dose. Of these, 153 subjects received 2 doses of Priorix Tetra with an interval between doses of 3 months and 147 subjects received Priorix and Varilrix. Seroconversion rates and geometric mean antibody concentrations/titres were similar to those observed after separate vaccination with Varilrix and Priorix. Seroconversion rates after a first dose of Priorix Tetra were comparable for all antigens except measles to those seen in 12-24 months old children in other clinical studies. The seroconversion rate reported for measles in infants 9 to 10 months of age following 1 dose of Priorix Tetra was 93.3% (95% CI: 87.6;96.9). Infants in their first year of life may not respond sufficiently to the components of the vaccine due to the possible interference with maternal antibodies. Therefore a second dose of Priorix Tetra should be given three months after the first dose.~~

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6.1 List of excipients

Powder:
Lactose anhydrous
Amino acids for injection (containing phenylalanine) ~~for injections~~
Mannitol
Sorbitol
Medium 199 (containing phenylalanine, para-aminobenzoic acid, sodium and potassium)

Solvent:
Water for injection

Residuals:
Neomycin sulphate

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העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://data.health.gov.il/Drugs/index.html#!/byDrug וניתן לקבלו מודפס על-ידי פניה לחברת גלקסוסמיתקליין
רח' בזל 25 פתח תקוה בטלפון: 03-9297100.

בברכה,

אביטל רוזנצויג

רוקחת ממונה