ספטמבר 2019

הנדון: BOOSTRIX / בוסטריקס
Suspension for injection

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לרופא של התכשיר BOOSTRIX / בוסטריקס. עדכון העלון כולל גם הרחבת התווית התכשיר מגיל עשר שנים לגיל ארבע שנים ועדכון סעיף משטר המינון .

חומרים פעילים:

-DIPHTHERIA TOXOID	2 IU / 0.5 ML
-TETANUS TOXOID	20 IU / 0.5 ML
-FILAMENTOUS HAEMAGGLUTININ (FHA)	8 MCG / 0.5 ML
-PERTUSSIS TOXOID (PT)	8 MCG / 0.5 ML
-PERTACTIN (PRN OR 69 KDA OMP)	2.5 MCG / 0.5 ML

ההתוויה העדכנית המאושרת לתכשיר בישראל:

For Booster vaccination against diphtheria, tetanus and pertussis of individuals from the age of four years onwards. The administration of Boostrix should be based on official recommendations

בהודעה זו מצויינים השינויים שבוצעו לעלון .

מקרא לעדכונים המסומנים:
תוספת – כתב אדום
מחיקה-כתב כחול עם קו מחיקה

להלן העידכונים המהותיים שנעשו בעלון לרופא:

Section	Marked update
4.1 Therapeutic indications	Boostrix is indicated for booster vaccination against diphtheria, tetanus and pertussis of individuals from the age of ~~ten~~four years onwards (see section 4.2). The administration of Boostrix ~~is not intended for primary immunisation~~should be based on official recommendations.
4.2 Posology and method of administration	Posology A single 0.5 ml dose of the vaccine is recommended. Boostrix may be administered from the age of ~~ten~~four years onwards. The use of Boostrix may be considered during the third trimester of pregnancy. For the use of the vaccine before the third trimester of pregnancy, see section 4.6. Boostrix should be administered in accordance with official recommendations and/or local practice regarding the use of vaccines ~~that provide low (adult) dose~~with reduced content of diphtheria, tetanus and pertussis antigens. ~~In subjects ≥ 40 years of age that had not received any diphtheria or tetanus containing vaccine in the past 20 years, one dose of Boostrix induces an antibody response against pertussis and protects against tetanus and diphtheria in the majority of cases. Two additional doses of a diphtheria and tetanus containing vaccine will maximize the vaccine response against diphtheria and tetanus when administered one and six months after the first dose (see section 5.1).~~

	Boostrix may be administered to adolescents and adults with unknown vaccination status or incomplete vaccination against diphtheria, tetanus and pertussis as part of an immunisation series against diphtheria, tetanus and pertussis. Based on data in adults, two additional doses of a diphtheria and tetanus containing vaccine are recommended one and six months after the first dose to maximize the vaccine response against diphtheria and tetanus (see section 5.1). …….
4.4 Special warnings and precautions for use	……. ~~Extremely rare cases of collapse or shock-like state (hypotonic-hyporesponsiveness episode) and convulsions within 2 to 3 days of vaccination have been reported in DTPa and DTPa-combination vaccines.~~ …….
4.5 Interaction with other medicinal products and other forms of interaction	……. Boostrix can be given concomitantly with meningococcal serogroups A, C, W-135 and Y (MenACWY) conjugate vaccines. Clinical studies in subjects aged 9 to 25 years demonstrated that the immune responses to the tetanus, diphtheria and meningococcal antigens were unaffected. Lower geometric mean concentrations (GMCs) were observed for the pertussis antigens; however, these data do not suggest clinically relevant interference. ……
4.6 Fertility, pregnancy and lactation	**Pregnancy** The use of Boostrix may be considered during the third trimester of pregnancy. For data relating to the prevention of pertussis disease in infants born to women vaccinated during pregnancy, see section 5.1. Safety data from a prospective observational study where Boostrix was administered to pregnant women during the third trimester (793 pregnancy outcomes) as well as data from passive surveillance where pregnant women were exposed to Boostrix or to Boostrix-IPV (dTpa-IPV vaccine) in the 3rd and 2nd trimester have shown no vaccine related adverse effect on pregnancy or on the health of the foetus/newborn child. Human data from prospective clinical studies on the use of Boostrix during the first and second trimester of pregnancy are not available. However, as with other inactivated vaccines, it is not expected that vaccination with Boostrix harms the foetus at any trimester of pregnancy. The benefits versus the risks of administering Boostrix during pregnancy should be carefully evaluated. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or post-natal development (see section 5.3). ~~As with other inactivated~~Limited data indicate that maternal antibodies may reduce the magnitude of the immune response to some vaccines~~, it is not expected that vaccination~~ in infants born from mothers vaccinated with Boostrix ~~harms the foetus.~~ ~~However, human data from prospective clinical studies on the use of Boostrix~~ during pregnancy~~ are not available. Therefore, the vaccine should be used during pregnancy only when clearly needed, and the possible advantages outweigh the possible risks for the foetus.~~ . The clinical relevance of this observation is unknown. …….

קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן.
העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h וניתן לקבלו מודפס על-ידי פניה לחברת גלקסוסמיתקליין רח' בזל 25 פתח תקוה בטלפון: 03-9297100.

בברכה,
ליליאנה בלטר
רוקחת ממונה