ספטמבר 2019

הנדון: BOOSTRIX POLIO / בוסטריקס פוליו
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 POLIO / בוסטריקס פוליו. עדכון העלון כולל גם הרחבת התווית התכשיר מגיל ארבע שנים לגיל שלוש 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
INACTIVATED POLIO VIRUS (IPV) TYPE 1	40 DU / 0.5 ML
INACTIVATED POLIO VIRUS (IPV) TYPE 2	8 DU / 0.5 ML
INACTIVATED POLIO VIRUS (IPV) TYPE 3	32 DU / 0.5 ML

ההתוויה העדכנית המאושרת לתכשיר בישראל:

For booster vaccination against diphtheria, tetanus and pertussis and poliomyelitis of individuals from the age of three years onwards. The administration of Boostrix Polio 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 Polio is indicated for booster vaccination against diphtheria, tetanus, pertussis and poliomyelitis of individuals from the age of ~~four~~ three years onwards (see section 4.2). ~~Boostrix Polio is not intended for primary immunisation.~~ The administration of Boostrix Polio 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 Polio may be administered from the age of ~~four~~ three years onwards. The use of Boostrix-IPV 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 Polio contains ~~low (adult) dose~~ reduced content of diphtheria, tetanus and pertussis antigens in combination with poliomyelitis antigens. Therefore, Boostrix Polio should be administered in accordance with official recommendations and/or local practice.

	~~In subjects ≥ 40 years of age that had not received any diphtheria or tetanus containing vaccine in the past 20 years (including those who have never been vaccinated or whose vaccination status was unknown), one dose of Boostrix Polio 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-IPV 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, pertussis and poliomyelitis. 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). Boostrix Polio can be used in the management of tetanus prone injuries in persons who have previously received a primary vaccination series of tetanus toxoid vaccine and for whom a booster against diphtheria, pertussis and poliomyelitis is indicated. Tetanus immunoglobulin should be administered concomitantly in accordance with official recommendations. Repeat vaccination against diphtheria, tetanus, pertussis and poliomyelitis should be performed at intervals as per official recommendations. *Paediatric population* The safety and efficacy of Boostrix Polio in children below ~~4~~3 years of age have not been established. ……..
4.4 Special warnings and precautions for use	……. A history ~~or~~ of febrile convulsions, a family history of convulsions and a family history of an adverse event following DTP vaccination do not constitute ~~contra-indications~~ contraindications. ……..
4.5 Interaction with other medicinal products and other forms of interaction	**Use with other vaccines or immunoglobulins** ~~Boostrix Polio may be administered concomitantly with human papilloma virus vaccine with no clinically relevant interference with antibody response to any of the components of either vaccine.~~ Boostrix-IPV may be administered concomitantly with any of the following monovalent or combination vaccines: measles, mumps, rubella, varicella (MMR/V) and human papilloma virus (HPV) vaccine with no clinically relevant interference with antibody response to any of the components of either vaccine (see section 4.8). ……..
4.6 Fertility, pregnancy and lactation	**Pregnancy** The use of Boostrix-Polio 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 (dTpa component of Boostrix-Polio) 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-Polio or to Boostrix 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-Polio 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-Polio harms the foetus at any trimester of pregnancy. The benefits versus the risks of administering Boostrix-IPV 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 ~~Polio harms the foetus.~~ ~~However, human data from prospective clinical studies on the use of Boostrix~~-IPV during pregnancy ~~are not available. Therefore, Boostrix Polio should be used during pregnancy only when clearly needed, and the possible advantages outweigh the possible risks for the foetus. No teratogenic effect~~. The clinical relevance of ~~vaccines containing diphtheria or tetanus toxoids, or inactivated poliovirus has been observed following use in pregnant women~~this observation is unknown. …….
4.8 Undesirable effects	……. *Coadministration with MMR/V vaccines in children aged 3-6 years* Boostrix-Polio was coadministered with MMR/V vaccines in 2 clinical studies with 406 children aged 3-6 years. In these studies, upper respiratory tract infection and rash were commonly reported. Fever, irritability, fatigue, loss of appetite and gastrointestinal disorders (including diarrhoea and vomiting) were reported with a higher frequency (very common) when compared to Table 1 while all other adverse reactions occurred at the same or lower frequency. Adverse reactions additionally reported during clinical ~~trials~~studies with ~~GlaxoSmithKline Biologicals' other reduced antigen content diphtheria-tetanus-acellular pertussis vaccine (~~Boostrix~~) where~~ (dTpa component of Boostrix ~~was~~-Polio), administered to 839 children (from 4 to 8 years of age) and 1931 adults, adolescents and children (from 10 to 76 years of age~~):~~) …….. ~~***- Subjects aged 4 - 8 years (N = 839)***~~ ~~Infections and infestations~~ ~~*Uncommon*: upper respiratory tract infection~~ ~~Gastrointestinal disorders~~ ~~*Common*: gastrointestinal disorders~~ ~~Skin and subcutaneous tissue disorders~~ ~~*Uncommon*: rash~~ ~~Data suggest that in subjects with DTP in childhood a booster dose might give an increase of local reactogenicity.~~

	Reactogenicity after repeat dose Data suggest that in subjects primed with DTP in childhood a second booster dose might give an increase of local reactogenicity. Subjects aged 15 years onwards without recent vaccination for diphtheria, tetanus, pertussis and poliomyelitis, who received a dose of Boostrix-Polio or another reduced-antigen content vaccine, followed by an additional dose of Boostrix-Polio 10 years after, showed no increased reactogenicity after this second dose compared to the first one. ……..

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