הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 05.2013)

תאריך 11-2014
שם תכשיר באנגלית ומספר הרישום: Infanrix Hexa (Reg. No.:133-20-30676)
שם בעל הרישום : GlaxoSmithKline (ISRAEL) Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

בעלון לרופא

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
… As for any vaccination, the risk-benefit of immunising with Infanrix hexa or deferring this vaccination should be weighed carefully in an infant or in a child suffering from a new onset or progression of a severe neurological disorder. … The physician should be aware that the rate of febrile reactions is higher when Infanrix hexa is co-administered with a pneumococcal conjugate vaccine (PCV7, PCV10, PCV13), or with a measles-mumps-rubella-varicella (MMRV) vaccine, compared to that occurring following the administration of Infanrix hexa alone. These reactions were mostly moderate (less than or equal to 39°C) and transient (see sections 4.5 and 4.8). Increased reporting rates of convulsions (with or without fever) and hypotonic hyporesponsive episode (HHE) were observed with concomitant administration of Infanrix hexa and Prevenar 13 (see section 4.8).	----------	**Special Warnings and Special Precautions for Use**
Infanrix hexa can be given concomitantly with pneumococcal conjugate vaccine (PCV7, PCV10 and PCV13), meningococcal serogroup C conjugate vaccine (CRM_{197} and TT conjugates), meningococcal serogroups A, C, W-135 and Y conjugate vaccine (TT conjugate), oral rotavirus vaccine and measles-mumps-rubella-varicella (MMRV) vaccine.	~~There are insufficient data with regard to the efficacy and safety of simultaneous administration of Infanrix hexa and Measles-Mumps-Rubella vaccine to allow any recommendation to be made.~~ ~~Data on concomitant administration of Infanrix hexa with Prevenar (pneumococcal saccharide conjugated vaccine,~~	**Interaction with other medicinal products and other forms of interaction**

Data have shown no clinically relevant interference in the antibody response to each of the individual antigens, although inconsistent antibody response to poliovirus type 2 in co-administration with Synflorix was observed (seroprotection ranging from 78% to 100%) and the immune response rates to the PRP (Hib) antigen of Infanrix hexa after 2 doses given at 2 and 4 months of age were higher if co-administered with a tetanus toxoid conjugate pneumococcal or meningococcal vaccine (see section 5.1). The clinical relevance of these observations remains unknown. Data from clinical studies indicate that, when Infanrix hexa is co-administered with pneumococcal conjugate vaccine, the rate of febrile reactions is higher compared to that occurring following the administration of Infanrix hexa alone. Data from one clinical study indicate that when Infanrix hexa is co-administered with measles-mumps-rubella-varicella (MMRV) vaccine, the rate of febrile reactions is higher compared to that occurring following the administration of Infanrix hexa alone and similar to that occurring following the administration of MMRV vaccine alone (see sections 4.4 and 4.8). The immune responses were unaffected. As with other vaccines it may be expected that in patients receiving immunosuppressive therapy, an adequate response may not be achieved.	~~adsorbed) have shown no clinically relevant interference in the antibody response to each of the individual antigens when given as a 3 dose primary vaccination (see section 4.4 for guidance on Prevenar and Prevenar 13).~~ ~~As with other vaccines it may be expected that in patients receiving immunosuppressive therapy, an adequate response may not be achieved~~	
Infections and infestations: Uncommon- Upper respiratory tract infection Blood and lymphatic system disorders: Rare- Lymphadenopathy[2], thrombocytopenia[2] Respiratory, thoracic and mediastinal disorders: Rare- Bronchitis, Apnoea[2] [see section 4.4 for apnoea in very premature infants (≤ 28 weeks of gestation)]	----------	**Adverse events**

Experience in co-administration: Analysis of postmarketing reporting rates suggests a potential increased risk of convulsions (with or without fever) and HHE when comparing groups which reported use of Infanrix hexa with Prevenar 13 to those which reported use of Infanrix hexa alone. … • Experience with hepatitis B vaccine: In extremely rare cases, allergic reactions mimicking serum sickness, paralysis, neuropathy, neuritis, hypotension, vasculitis, lichen planus, erythema multiforme, arthritis, muscular weakness, Guillain-Barré syndrome, encephalopathy, encephalitis and meningitis have been reported. The causal relationship to the vaccine has not been established.		

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב ועל רקע ירוק.
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע ירוק.