**הודעה על החמרה (מידע בטיחות) בעלון לרופא**

**תאריך \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_20/02/2013\_\_\_\_\_\_\_**

**שם תכשיר באנגלית ומספר הרישום \_\_\_\_Prevenar 13 (**[143 54 33058 00](http://www.old.health.gov.il/units/pharmacy/trufot/PerutTrufa.asp?Reg_Number=143%2054%2033058%2000&safa=))

**שם בעל הרישום \_ניאופרם בע"מ\_**

**ההחמרות המבוקשות:**

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| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **Special warnings and precautions for use** |  | When Prevenar 13 is administered concomitantly with Infanrix hexa (DTPa‑HBV-IPV/Hib), the rates of febrile reactions are similar to those seen with concomitant administration of Prevenar (7-valent) and Infanrix hexa (see section 4.8). |
| **Interaction with other medicinal products and other forms of interaction** | Infants and children aged 8 weeks to 5 yearsPrevenar 13 can be given with any of the following vaccine antigens, either as monovalent or combination vaccines: diphtheria, tetanus, acellular or whole cell pertussis, *Haemophilus influenzae* type b, inactivated poliomyelitis, hepatitis B, meningococcal serogroup C, measles, mumps, rubella and varicella. Clinical studies demonstrated that the immune responses and the safety profiles of the administered vaccines were unaffected.In clinical studies, where there was concomitant administration of Prevenar 13 and rotavirus vaccine, no change in the safety profiles of these vaccines was observed. | Infants and children aged 8 weeks to 5 yearsPrevenar 13 can be given concomitantly with any of the following vaccine antigens, either as monovalent or combination vaccines: diphtheria, tetanus, acellular or whole cell pertussis, *Haemophilus influenzae* type b, inactivated poliomyelitis, hepatitis B, meningococcal serogroup C, measles, mumps, rubella ~~and~~,varicella ~~Clinical studies demonstrated that the immune responses and the safety profiles of the administered vaccines were unaffected~~ and rotavirus vaccine. ~~In clinical studies, where there was concomitant administration of Prevenar 13 and rotavirus vaccine, no change in the safety profiles of these vaccines was observed.~~ |
| **Undesirable effects**  |  | In a clinical study in infants vaccinated at 2, 3, and 4 months of age, fever ≥ 38°C was reported at higher rates among infants who received Prevenar (7-valent) concomitantly with Infanrix hexa (28.3% to 42.3%) than in infants receiving Infanrix hexa alone (15.6% to 23.1%). After a booster dose at 12 to 15 months of age, the rate of fever ≥ 38°C was 50.0% in infants who received Prevenar (7-valent) and Infanrix hexa at the same time as compared to 33.6% in infants receiving Infanrix hexa alone. These reactions were mostly moderate (less than or equal to 39 °C) and transient. |