פייזר פרמצבטיקה ישראל בע"מ
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אוקטובר 2024

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על תוספת התוויה עבור התכשיר **Prevenar 20**

העדכון בעלונים לרופא וצרכן של התכשיר כוללים תוספת התוויה, תוספת משטר מינון ותוספת של מידע בטיחותי

שם התכשיר:

Prevenar 20

המרכיב הפעיל:

PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 23F 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 19 F 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 14 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 9V 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 7F 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 6B 4.4 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 5 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 4 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 1 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 3 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 6A 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 18C 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 19A 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 33F 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 22F 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 15B 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 12F 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 11A 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 10A 2.2 MCG / 0.5 ML
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 8 2.2 MCG / 0.5 ML

התוויות מאושרות :

Prevenar 20 is indicated for:

•Active immunisation for the prevention of pneumococcal disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F,23F and 33F in individuals from 6 weeks of age and less than 18 years of age.

•Active immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in individuals 18 years of age and older.

להלן העדכונים העיקריים בעלון לרופא :

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Active immunisation for the prevention of pneumococcal disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals from 6 weeks of age and less than 18 year of age.

4.2 Posology and method of administration

Posology

Paediatric population

The safety and efficacy of Prevenar 20 in infants below 6 weeks of age have not been established. No data are available.

No or only limited data are available for Prevenar 20 in preterm, older unvaccinated, or partially vaccinated infants and children (see sections 4.4, 4.8 and 5.1). The following dosing recommendations are predominantly based on experience with Prevenar 13.

Infants and children 6 weeks to less than 5 years of age

It is recommended that infants who receive a first dose of Prevenar 20 complete the vaccination course with Prevenar 20.

Vaccination schedule in infants and children 6 weeks to 15 months of age	
3-dose series (two-dose primary series followed by a booster dose)	The recommended immunisation series for Prevenar 20 given as part of a routine infant immunisation program, consists of three doses, each of 0.5 mL. The first dose is usually given at 2 months of age, with a second dose 2 months later. The first dose may be given as early as 6 weeks of age. The third (booster) dose is recommended between 11 and 15 months of age (see section 5.1).
4-dose series (three-dose primary series followed by a booster dose)	Prevenar 20 may be given as a 4-dose series, each of 0.5 mL. The primary infant series consists of three doses, with the first dose usually given at 2 months of age and with an interval of at least 4 weeks between doses. The first dose may be given as early as 6 weeks of age. The fourth (booster) dose is recommended between 11 and 15 months of age (see section 5.1).
Preterm infants (less than 37 weeks of gestation)[a]	The recommended immunisation series for Prevenar 20 consists of four doses, each of 0.5 mL. The primary infant series consists of three doses, with the first dose given at 2 months of age and with an interval of at least 4 weeks between doses. The first dose may be given as early as 6 weeks of age. The fourth (booster) dose is recommended between 11 and 15 months of age (see sections 4.4 and 5.1).
Vaccination schedule for infants and children less than 15 months of age transitioning from another pneumococcal conjugate vaccine[b]	
Prior vaccination with another pneumococcal conjugate vaccine	Infants and children who have begun immunisation with another pneumococcal conjugate vaccine may complete immunisation by transitioning to Prevenar 20 at any point in the schedule.
Catch-up vaccination schedule for infants and children 7 months to less than 18 years of age	

Unvaccinated infants 7 to less than 12 months of age[a]	Two doses, each of 0.5 mL, with an interval of at least 4 weeks between doses. A third dose is recommended in the second year of life.
Unvaccinated children 12 to less than 24 months of age[a]	Two doses, each of 0.5 mL, with an interval of at least 8 weeks between doses.
Unvaccinated children 2 to less than 5 years of age[a]	One single dose of 0.5 mL.
Children 15 months to less than 5 years of age previously vaccinated with a pneumococcal conjugate vaccine	1 dose (0.5 mL). If a previous pneumococcal conjugate vaccine was administered, at least 8 weeks should elapse before administering Prevenar 20 (see section 5.1).
Children 5 to less than 18 years of age regardless of prior pneumococcal conjugate vaccination	1 dose (0.5 mL). If a previous pneumococcal conjugate vaccine was administered, at least 8 weeks should elapse before administering Prevenar 20 (see section 5.1).

a. In preterm and unvaccinated infants and children 7 months to less than 5 years of age, Prevenar 20 is expected to perform similarly to Prevenar 13, a pneumococcal conjugate vaccine consisting of 13 polysaccharide conjugates that are also in Prevenar 20.

b. The safety and immunogenicity of Prevenar 20 administered to infants and children less than 15 months of age who have begun vaccination with another pneumococcal conjugate vaccine have not been established. However, safety and immunogenicity studies with a transition from a lower valent to higher valent pneumococcal conjugate vaccine are relevant to Prevenar 20. Based on clinical experience and relevant randomised controlled trials, the recommended transition from a lower to a higher valent pneumococcal conjugate vaccine may be considered in guiding vaccination with Prevenar 20 for infants and children who have not yet completed the infant vaccination series.

להלן העדכונים העיקריים בעלון לצרכן :

1. למה מיועדת התרופה?

חיסון פעיל למניעת מחלה פנאומוקוקלית הנגרמת על ידי סרוטיפים של *Streptococcus pneumoniae* 1, 3, 4, 5, 6A, 6B 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F בתינוקות, בילדים ובמתבגרים, מגיל 6 שבועות ועד גיל פחות מ- 18 שנים.

השינויים המוצגים הינם השינויים העיקריים . כמו כן, בוצעו שינויים נוספים בעלון לרופא ובעלון לצרכן הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח אשר אינם מוצגים בהודעה זו .
קיימים עדכונים נוספים.
העלונים המעודכנים נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
https://www.health.gov.il/Subjects/PharmAndCosmetics/DrugsRegistryDB/Pages/DrugsDatabase.aspx

לחילופין, לקבלת עלונים מלאים מודפסים ניתן לפנות לחברת פייזר פי אף אי פרמצבטיקה ישראל בע"מ שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.
בברכה,
אנה רזניקוב
רוקחת ממונה