פייזר פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501
פייזר פרמצבטיקה ישראל בע"מ

מרץ 2020

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלונים לרופא של **Prevenar :**

המרכיב הפעיל:
PNEUMOCOCCAL POLYSACCHARIDE SEROTYPE 23F,19F,14, 9V, 7F, 5,4,1,3,6A,18C 19A 2.2 MCG / 0.5 ML, 6B 4.4 MCG / 0.5 ML

Indicated for:
Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants, children and adolescents from 6 weeks to 17 years of age.
Active immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in adults ≥ 18 years of age and the elderly

להלן העדכונים העיקריים בעלון לרופא:

5 WARNINGS AND PRECAUTIONS

5.1 Pharmacodynamic properties

Prevenar 13 is estimated to cover over 90% of serotypes causing antimicrobial ~~antibiotic~~ - resistant IPD.

Efficacy study in adults 65 years and older

….

A first episode of hospitalised, chest X ray confirmed pneumonia was identified in about 2% of this population (n=1,814 subjects) of which 329 cases were confirmed pneumococcal CAP and 182 cases were VT pneumococcal CAP in the per protocol and modified intent to treat (mITT) populations. ~~For the primary endpoint (per protocol population), there were 139 (49 Prevenar 13: 90 Placebo) first episodes of VT-CAP resulting in an efficacy of 45.56% (95.2% CI, 21.82-62.49; p=0.0006).~~

Efficacy was ~~also~~ demonstrated for the primary and ~~two~~ secondary endpoints in the per protocol population (Table 5). ~~For the non bacteraemic/non-invasive (NB/NI) pneumococcal CAP secondary endpoint, there were 93 (33 Prevenar 13: 60 Placebo) first episodes of NB/NI VT pneumococcal CAP resulting in an efficacy of 45.00% (95.2% CI, 14.21-65.31; p=0.0067). For the IPD secondary endpoint, there were 35 (7 Prevenar 13: 28 Placebo) first episodes of VT-IPD, resulting in an efficacy of 75.00% (95.2% CI, 41.06-90.87; p=0.0005).~~

Table 5: Vaccine efficacy (VE) for the primary and secondary endpoints of the CAPiTA study (per protocol population)					
Efficacy endpoint	**Cases**			**VE (%) (95.2% CI)**	**p-value**
	Total	**Prevenar 13 group**	**Placebo group**		
Primary endpoint					
First episode of confirmed VT pneumococcal CAP	139	49	90	45.56 (21.82, 62.49)	0.0006
Secondary endpoints					
First episode of confirmed NB/NI[1] vaccine type pneumococcal CAP	93	33	60	45.00 (14.21, 65.31)	0.0067
First episode of VT-IPD[2]	35	7	28	75.00 (41.06, 90.87)	0.0005
[1]NB/NI – non-bacteraemic/non-invasive [2]VT-IPD – vaccine-type invasive pneumococcal disease					

A post-hoc analysis was used to estimate the following public health outcomes against clinical CAP (as defined in the CAPiTA study, and based on clinical findings regardless of radiologic infiltrate or etiologic confirmation): vaccine efficacy (VE), incidence rate reduction (IRR), and number needed to vaccinate (NNV) (Table 6).

IRR, also referred to as vaccine preventable disease incidence, is the number of cases of vaccine preventable disease per 100,000 person-years of observation.

In Table 6, NNV is a measure that quantifies the number of people that need to be vaccinated in order to prevent one clinical CAP case.

Table 6: Vaccine efficacy (VE) against clinical CAP*							
	Episodes		**Vaccine efficacy[1] % (95% CI) (1-sided p-value)**	**Incidence per 100,000 person-years of observation (PYO)**		**Incidence rate reduction[2] (95% CI)**	**Number needed to vaccinate[3]**
	Prevenar 13	**Placebo**		**Prevenar 13**	**Placebo**		
All episodes analysis	1375	1495	8.1 (-0.6, 16.1) (0.034)	819.1	891.2	72.2 (-5.3, 149.6)	277
First episode analysis	1126	1214	7.3 (-0.4, 14.4) (0.031)	670.7	723.7	53.0 (-2.7, 108.7)	378
* Patients with at least 2 of the following: Cough; purulent sputum, temperature >38°C or <36.1°C; pneumonia (auscultatory findings); leukocytosis; C-reactive protein value >3 times the upper limit of normal; hypoxemia with a partial oxygen pressure <60 mm Hg while breathing room air. [1] A Poisson regression model with random effects was used to calculate VE. [2] Per 100,000 person-years of observation. IRR is calculated as the incidence in the placebo group minus the incidence in the vaccine group, and was mathematically equivalent to VE × the incidence in the placebo group. [3] Based on a 5-year duration of protection. NNV is not a rate but instead indicates the number of cases prevented for a given number of persons vaccinated. NNV also incorporates the length of the trial or duration of protection and is calculated as 1 divided by the product of the IRR and duration of protection (or length of trial) (=1/(IRR × duration).							

7. Manufacturer

John Wyeth and Brother Limited: Trading as Wyeth Pharmaceuticals
New Lane, Havant, Hampshire, PO9 2NG, UK.
Or
Pfizer Manufacturing Belgium NV, Puurs, Belgium

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.

העלון המעודכן נשלח למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
https://data.health.gov.il/drugs/index.html#!/byDrug

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133 , הרצליה פיתוח, 46725.

בברכה,
אורטל עבודי
רוקחת ממונה