ABBREVIATED PRESCRIBING INFORMATION

Prevenar 13® suspension for injection
Pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)

Presentation: Each 0.5ml dose of Prevenar 13 contains 2.2 micrograms of each of the following polysaccharide serotypes: 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F and 4.4 micrograms of polysaccharide serotype 6B. Each polysaccharide is conjugated to the CRM_{197} carrier protein and adsorbed on aluminium phosphate. 1 dose (0.5 ml) contains approximately 32 µg CRM_{197} carrier protein and 0.125 mg aluminium.

Indications: Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants and children 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. The use of Prevenar 13 should be determined on the basis of official recommendations taking into consideration the impact of invasive disease and pneumonia in different age groups as well as the variability of serotype epidemiology in different geographical areas.

Dosage and Administration: For intramuscular injection.

It is recommended that infants who receive a first dose of Prevenar 13 complete the vaccination course with Prevenar 13.

Infants aged 6 weeks-6 months:

Three-dose primary series: The recommended immunisation series consists of four doses. 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 1 month between doses. The first dose may be given as early as six weeks of age. The fourth (booster) dose is recommended between 11 and 15 months of age.

Two-dose primary series: Alternatively, when Prevenar 13 is given as part of a routine infant immunisation programme, a series consisting of three doses may be given. The first dose may be administered from the age of 2 months, with a second dose 2 months later. The third (booster) dose is recommended between 11 and 15 months of age.

Preterm infants (< 37 weeks gestation):

In preterm infants, the recommended immunisation series 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 1 month between doses. The first dose may be given as early as six weeks of age. The fourth (booster) dose is recommended between 11 and 15 months of age.

Unvaccinated infants and children ≥ 7 months of age:

Infants aged 7-11 months: Two doses, with an interval of at least 1 month between doses. A third dose is recommended in the second year of life.

Children aged 12-23 months: Two doses, with an interval of at least 2 months between doses.

*Children **and adolescents** aged 2-17 years:* One single dose.

Prevenar 13 vaccine schedule for infants and children previously vaccinated with Prevenar (7-valent) (*Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F)

Infants and children who have begun immunisation with Prevenar may switch to Prevenar 13 at any point in the schedule.

Children aged 12-59 months: Children who are considered completely immunised with Prevenar (7-valent) should received one dose of 0.5ml of Prevenar 13 to elicit immune responses to the additional 6 serotypes. This dose of Prevenar 13 should be administered at least 8 weeks after the final dose of Prevenar (7-valent)

*Children **and adolescents** aged 5-17 years:* One single dose of Prevenar 13 if they have been previously vaccinated with one or more doses of Prevenar. This dose of Prevenar 13 should be administered at least 8 weeks after the final dose of Prevenar (7-valent).

Adults ≥18 years of age and the elderly*:* One single dose.

The need for revaccination with a subsequent dose of Prevenar 13 has not been established.

Regardless of prior pneumococcal vaccination status, if the use of 23 valent pneumococcal polysaccharide vaccine is considered appropriate, Prevenar 13 should be given first.

Special Populations: Individuals who have underlying conditions predisposing them to invasive pneumococcal disease (such as sickle cell disease or HIV infection) including those previously vaccinated with one or more doses of 23-valent pneumococcal polysaccharide vaccine may receive at least one dose of Prevenar 13. In individuals with an haematopoietic stem cell transplant (HSCT), the recommended immunisation series consists of four doses of Prevenar 13, each of 0.5 ml. The primary series consists of

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three doses, with the first dose given at 3 to 6 months after HSCT and with an interval of at least 1 month between doses. A fourth (booster) dose is recommended 6 months after the third dose.

Contra-indications: Hypersensitivity to the active substances, to any of the excipients, or to diphtheria toxoid. As with other vaccines, the administration of Prevenar 13 should be postponed in subjects suffering from acute, severe febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

Warnings and Precautions: Do not administer intravascularly. Appropriate medical treatment and supervision must be available in case of anaphylaxis. It should not be given to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection, but may be given subcutaneously if the potential benefit clearly outweighs the risks. Prevenar 13 will only protect against *Streptococcus pneumoniae* serotypes included in the vaccine, and will not protect against other microorganisms that cause invasive disease, pneumonia, or otitis media. As with any vaccine, Prevenar 13 may not protect all individuals receiving the vaccine from pneumococcal disease. Individuals with impaired immune responsiveness, whether due to the use of immuno-suppressive therapy, a genetic defect, human immunodeficiency virus (HIV) infection, or other causes, may have reduced antibody response to active immunisation. Safety and immunogenicity data are available for a limited number of individuals with sickle cell disease, HIV infection, or with an HSCT. Safety and immunogenicity data for Prevenar 13 are not available for individuals in other specific immuno-compromised groups (e.g., malignancy, or nephrotic syndrome) and vaccination should be considered on an individual basis.

Infants and children aged 6 weeks to 5 years:

Limited data have demonstrated that Prevenar 7 valent (three-dose primary series) induces an acceptable immune response in infants with sickle cell disease with a safety profile similar to that observed in non-high-risk groups. Children younger than 2 years old should receive the appropriate-for-age Prevenar 13 vaccination series. The use of pneumococcal conjugate vaccine does not replace 23-valent polysaccharide vaccine in at risk children ≥ 2 years of age. Children ≥ 2 years of age at high risk, previously immunised with Prevenar 13 should receive 23-valent pneumococcal polysaccharide vaccine whenever recommended. The potential risk of apnoea and the need for respiratory monitoring for 48-72 hours should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. 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. Increased reporting rates of convulsions (with or without fever) and hypotonic hyporesponsive episode (HHE) were observed with concomitant administration of Prevenar 13 and Infanrix hexa. Antipyretic treatment should be initiated according to local treatment guidelines for children with seizure disorders or a prior history of febrile seizures, or when vaccinating simultaneously with whole cell pertussis vaccines.

Adults aged 50 years and older: When Prevenar 13 was given concomitantly with trivalent inactivated influenza vaccine (TIV), the immune responses to Prevenar 13 were lower compared to when Prevenar 13 was given alone, however, there was no long-term impact on circulating antibody levels. The immune responses to Prevenar 13 were noninferior when Prevenar 13 was given concomitantly with quadrivalent inactivated influenza vaccine (QIV) compared to when Prevenar 13 was given alone. As with concomitant administration with trivalent vaccines, immune responses to some pneumococcal serotypes were lower when both vaccines were given concomitantly.

Fertility, Pregnancy & Lactation: There are no data from the use of pneumococcal 13-valent conjugate vaccine in pregnant women. It is unknown whether pneumococcal 13-valent conjugate is excreted in human milk.

Side Effects: 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 Prevenar 13 with Infanrix hexa to those which reported use of Prevenar 13 alone. Adverse reactions reported in clinical studies or from the post-marketing experience for all age groups are listed in this section per system organ class, in decreasing order of frequency and seriousness. The frequency is defined as follows: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from available data).

Infants and children aged 6 weeks to 5 years:

Very common (≥ 1/10): Decreased appetite, fever, pyrexia, irritability, any injection-site reactions (including erythema, induration/swelling [2.5 cm – 7.0 cm after booster dose and in older children, aged 2 to 5 years] or pain/tenderness), drowsiness, restless sleep. **Common** (≥ 1/100 to < 1/10): Vomiting,

diarrhoea, rash, fever over 39 °C, injection-site movement impairment (due to pain), injection-site erythema or induration/swelling 2.5 cm – 7.0 cm (after infant series). **Uncommon** (≥ 1/1,000 to < 1/100): Convulsions (including febrile convulsions), urticaria or urticaria-like rash, injection-site erythema, induration/swelling > 7.00 cm, crying. **Rare** (≥ 1/10,000 to < 1/1,000): Hypersensitivity reaction including face oedema, dyspnoea, bronchospasm, hypotonic-hyporesponsive episode. Not known: anaphylactic/anaphylactoid reaction including shock, angioedema, injection-site urticaria, injection-site dermatitis, injection-site pruritis, flushing. Lymphadenopathy (localised to the region of the injection site), erythema multiforme. In clinical studies 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 than in infants receiving Infanrix hexa alone. After a booster dose at 12 and 15 months of age, the rate of fever ≥ 38°C was greater in infants who received Prevenar (7 valent) and Infanrix hexa at the same time compared to infants receiving Infanrix hexa alone. These reactions were mostly moderate (less than or equal to 39°C) and transient. ***Additional information in special populations:*** Apnoea in very premature infants (≤ 28 weeks of gestation).

Children and adolescents aged 6 to 17 years of age: Very common (≥ 1/10): Decreased appetite, irritability, any vaccination-site erythema, induration/swelling or pain/tenderness, somnolence, poor quality sleep, vaccination-site tenderness (including impaired movement) **Common** (≥ 1/100 to < 1/10): Headaches, vomiting, diarrhoea, rash, urticaria or urticaria-like rash, pyrexia. ***Additional information in special populations:*** Children and adolescents with sickle cell disease, HIV infection or an HSCT have similar frequencies of adverse reactions, except that headaches, vomiting, diarrhoea, pyrexia, fatigue, arthralgia, and myalgia were very common.

Adults ≥18 years of age, and the elderly: Very common (≥ 1/10): Decreased appetite, headaches, diarrhoea, vomiting, rash, chills; fatigue; injection-site erythema; injection-site induration/swelling; injection-site pain/tenderness; limitation of arm movement, arthralgia; myalgia. **Common** (≥ 1/100 to < 1/10): Vomiting, pyrexia. **Uncommon** (≥ 1/1,000 to < 1/100): Nausea, hypersensitivity reaction including face oedema, dyspnoea, bronchospasm, lymphadenopathy localized to the region of the injection site. ***Additional information in special populations***: Adults with HIV infection have similar frequencies of adverse reactions, except that pyrexia and vomiting were very common and nausea common. Adults with an HSCT have similar frequencies of adverse reactions, except that pyrexia and vomiting were very common.

Legal Category: POM. **Package Quantities:** Pack of 1 single-dose pre-filled syringe (with separate needle) or pack of 10 single-dose pre-filled syringes. **Cost:** There is no cost to immunisers supplied under the UK routine childhood immunisation programme. Cost for supply outside the UK routine childhood immunisation programme: Single-dose pre-filled syringe (with separate needle) pack of 1: £49.10; single-dose pre-filled syringe pack of 10: £491.

Marketing Authorisation Numbers: Single-dose pre-filled syringe (with separate needle) pack of 1: EU/1/09/590/002, single-dose pre-filled syringe pack of 10: EU/1/09/590/003

Marketing Authorisation Holder: Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium.

For full prescribing information and details of other side effects see Summary of Product Characteristics

Further information is available on request from Medical Information Department at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Pfizer Medical Information on 01304 616161

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