PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (ADSORBED), 13-VALENT

PREVENAR 13* Multidose Vial

DESCRIPTION

PREVENAR 13 (pneumococcal 13-valent conjugate vaccine) is a sterile suspension. The vaccine is composed of saccharides of the capsular antigen of *Streptococcus pneumoniae* (*S. pneumoniae*), serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, individually conjugated to diphtheria CRM_{197} protein, a nontoxic variant of diphtheria toxin.

PREVENAR 13 is manufactured as a liquid preparation. After shaking, the vaccine is a homogenous, white suspension.

PREVENAR 13 Multidose vial contains the preservative 2-Phenoxyethanol

COMPOSITION	**Paediatric Dose**
Volume per dose	0.5 mL
Pneumococcal polysaccharide for serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F & 23F	2.2 µg of each
Pneumococcal polysaccharide for serotype 6B	4.4 µg
Diphtheria protein CRM_{197}	~32 µg
Aluminum as aluminum phosphate adjuvant	0.125 mg
2-Phenoxyethanol as preservative	4.0 mg
Other ingredients:	
Polysorbate 80	
Succinic acid	
Sodium chloride	
Water-for-injection	

ADMINISTRATION

Shake well before use to homogenize the suspension, and only use if the vaccine is a homogenous, white suspension. Use a new sterile syringe and sterile needle for each injection.

The dose is 0.5 mL given intramuscularly, with care to avoid injection into or near nerves and blood vessels. The preferred sites are the anterolateral aspect of the thigh in infants or the deltoid muscle of the upper arm in older children and adults. The vaccine should not be injected in the gluteal area.

IMMUNIZATION SCHEDULE

Active immunization of infants, children, and adolescents from 6 weeks through 17 years of age against invasive disease, pneumonia and otitis media caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.

Active immunization of adults, aged 18 years and older, against pneumonia and invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.

Infants and Children

PREVENAR 13 may be given to infants and children 6 weeks to 5 years of age at the same time as diphtheria, tetanus, acellular or whole-cell pertussis, *Haemophilus influenzae* type b, inactivated poliomyelitis, hepatitis B, meningococcal serogroup C, measles, mumps, rubella and varicella vaccines. When rotavirus or hepatitis A vaccines were given with PREVENAR 13, the safety profiles were similar, but immunogenicity was not measured.

PREVENAR 13 can also be given concomitantly between 12-23 months with the tetanus toxoid conjugated meningococcal polysaccharide serogroups A, C, W and Y vaccine to children who were primed with PREVENAR 13 in their first year of life.

No data are currently available regarding concomitant use with other vaccines in children and adolescents aged 6 to 17 years.

The use of PREVENAR 13 should be based on official recommendations, taking into consideration the risk of invasive disease in different age groups, underlying comorbidities as well as variability of serotype epidemiology in different geographical areas.

Primary Immunization

For infants, the immunization series of PREVENAR 13 consists of three primary doses of 0.5 mL each. The first dose may be given as early as 6 weeks of age, with a minimum of 4 weeks between doses. A fourth, booster dose is recommended after the first birthday.

Alternatively, when PREVENAR 13 is given as part of a routine infant immunization programme, a three-dose schedule may be considered. The first dose may be given from the age of 2 months, with a second dose 2 months later, and a third (booster) dose is recommended between 11 to 15 months of age.

PREVENAR 13 may be given to infants with sickle cell disease or HIV infection as per age-based recommendations.

For Preterm infants (<37 weeks gestation)

In preterm infants, the recommended immunization 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.

For Previously Unvaccinated Older Children

For previously unvaccinated, older infants and children who are beyond the age of routine infant immunization, other schedules are recommended:

- Infants 7 to 11 months of age at first dose: three doses total (two doses at least 4 weeks apart, third dose after the first birthday and at least 2 months after the second dose)

- Children 12 to 23 months of age at first dose: two doses at least 2 months apart

Alternatively, when PREVENAR 13 is routinely given as part of a generalized infant immunization programme, a single dose may be considered in previously unvaccinated children aged 12 to 23 months.

- Children and adolescents 2 to 17 years of age at first dose: one dose

For Children Previously Vaccinated with PREVENAR

PREVENAR 13 contains the same 7 serotypes contained in Prevenar (pneumococcal 7-valent conjugate) vaccine and is manufactured based on the same conjugate technology, using the same carrier protein CRM_{197}. Children who have begun immunization with pneumococcal 7-valent conjugate vaccine may complete immunization by switching to PREVENAR 13 at any point in the schedule. In clinical trials, immunogenicity and safety profiles were comparable. A single dose of PREVENAR 13 in children 12 to 59 months of age has been shown to induce immunity to the six additional serotypes.

Children and adolescents 5 to 17 years of age may also receive a single dose of PREVENAR 13 if they have been previously vaccinated with one or more doses of pneumococcal 7-valent conjugate vaccine. This dose of PREVENAR 13 should be administered at least 8 weeks after the final dose of Prevenar (pneumococcal 7-valent conjugate).

Adults aged 18 years and older

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.

PREVENAR 13 may be administered concomitantly with the seasonal trivalent or quadrivalent inactivated influenza vaccine (TIV or QIV) in adults aged 50 years and older.

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 hematopoietic stem cell transplant (HSCT), the recommended immunization series consists of four doses of PREVENAR 13, each of 0.5 mL. The primary series consists of 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.

SIDE EFFECTS

Infants and children aged 6 weeks to 5 years

The most frequently reported adverse reactions included injection site reaction, fever, irritability, drowsiness, restless sleep, decreased appetite, vomiting, diarrhea, and rash. Risks are associated with all vaccines.

Children and adolescents aged 6 to 17 years

The most frequently reported adverse reactions included headaches, decreased appetite, vomiting, diarrhea, rash, urticaria or urticaria like rash, irritability, any vaccination-site erythema; induration, swelling or pain/tenderness, drowsiness, poor quality sleep, vaccination-site tenderness (including impaired movement), and fever.

Children and adolescents with sickle cell disease, HIV infection, or an hematopoietic stem cell transplant have similar frequencies of adverse reactions, except that headaches, vomiting, diarrhea, fever, fatigue, arthralgia, and myalgia were very common.

Adults aged 18 years and older

The most frequently reported adverse reactions included pain or tenderness at the injection site, fatigue, headache, muscle pain, joint pain, decreased appetite, diarrhea, vomiting, fever, injection site redness, injection site swelling, limitation of arm movement, chills and rash. PREVENAR 13 does not provide 100% protection against vaccine serotypes or protect against non-vaccine serotypes.

Adults with HIV infection have similar frequencies of adverse reactions, except that fever and vomiting were very common and nausea common.

Adults with an hematopoietic stem cell transplant have similar frequencies of adverse reactions, except that fever and vomiting were very common.

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine, including diphtheria toxoid.

STORAGE

Transport and store refrigerated at +2ºC to +8ºC.

DO NOT FREEZE. Discard if the vaccine has been frozen.

Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of Prevenar 13 from which one or more doses of vaccine have been removed during an immunisation session may be used in subsequent immunization sessions for up to a maximum of 28 days provided that all of the following conditions are met:

- The expiry date has not passed.
- The vaccines are stored under appropriate cold chain conditions.
- The vaccine vial septum has not been submerged in water.
- Aseptic technique has been used to withdraw all doses.
- The vaccine vial monitor (VVM), if attached, has not reached the discard point (see Figure 1).

PRESENTATION

Vial, containing 4 x 0.5 ml Doses (25 or 50 vials per package)

Pfizer

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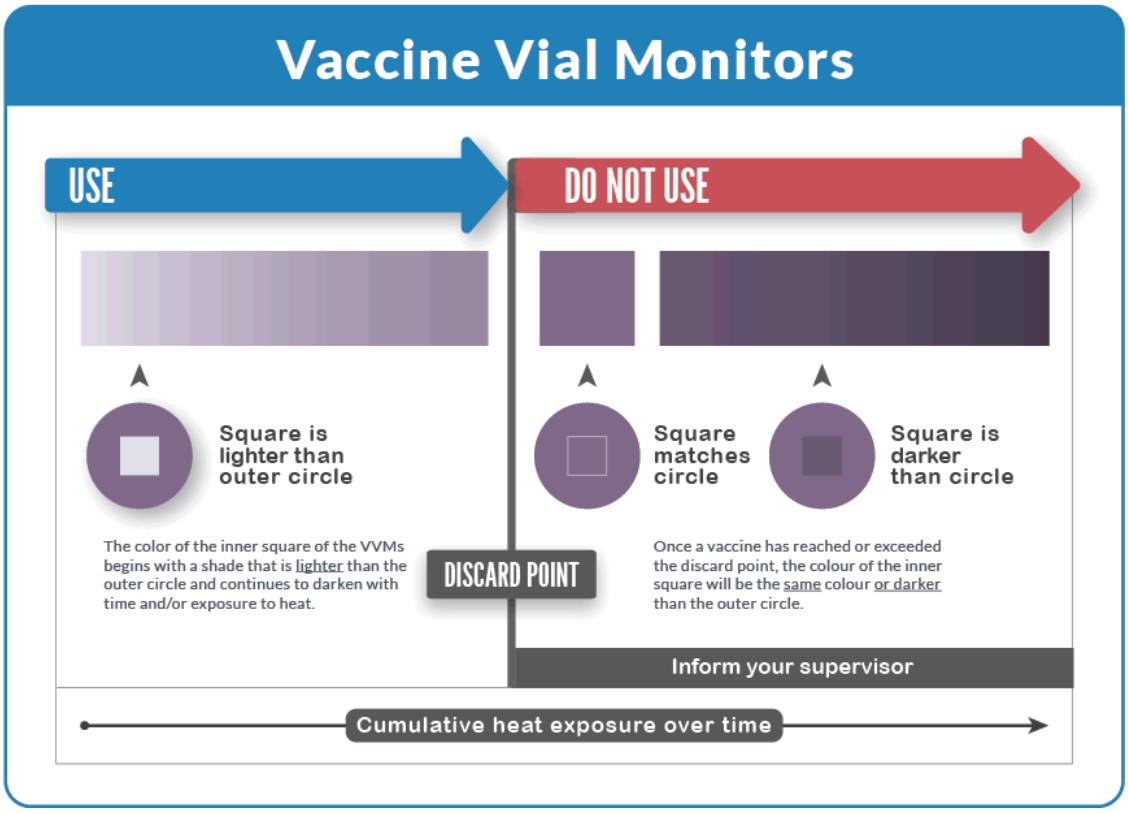
Figure 1: How to read a vaccine vial monitor



Vaccine Vial Monitors (VVMs) have been applied to the vial label on all PREVENAR 13 Multidose Vials manufactured by Pfizer. The colour dot which appears on the vial label is the VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, then the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, then the vial should be discarded.