PREVENAR 13®
Abbreviated Prescribing Information / Summary of Product Information

GENERIC NAME: Pneumococcal Polysaccharide Conjugate Vaccine [Adsorbed] I.P., 13-Valent

PRESENTATION: Pre-filled syringe. 0.5 ml suspension for Injection in pre-filled syringe (Type I glass) with a plunger rod(polypropylene) and the syringe packaging includes hypodermic needle. Pack sizes of 1, 5, 10, 25 and 50. Not all presentation and pack sizes may be marketed.

INDICATION(s):

- For active immunization for the prevention of Pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F (including sepsis, meningitis, bacteraemia, pneumonia) and acute otitis media in infants and children from 6 weeks to 5 years of age.
- For active immunization for the prevention of Pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in children of 6 years to 17 years of age.
- For active immunization for the prevention of Pneumonia and invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults of 18 years to 49 years of age.
- For active immunization for the prevention of Pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults of 50 years and older age group.

DOSAGE AND ADMINISTRATION: (For intramuscular use only)

- For infants, the immunization series of Prevenar 13 consists of 3 doses of 0.5ml each at 6 weeks, 10 weeks and 14 weeks of age, followed by a fourth dose of 0.5 ml at 12-15 months of age. The customary age for the first dose is 2 months of age, but it can be given as young as 6 weeks of age. The recommended dosing interval is 4 to 8 weeks. The fourth dose should be administered at least 2 months after the third dose.
- For children 6 years to 17 years of age, 1 dose of 0.5 mL Prevenar 13
- Adults ≥18 years of age, One single dose.
- For adults 50 years of age and older, Prevenar13 is to be administered as a single dose, including for those previously vaccinated with a pneumococcal polysaccharide vaccine.

The vaccine should be given by intramuscular injection. The preferred sites are the anterolateral aspect of the thigh (vastus lateralis muscle) in infants or the deltoid muscle of the upper arm in children and adults.

Prevenar 13 has been shown to be safe and immunogenic in the geriatric population. 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 a 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 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

CONTRAINDICATIONS: Hypersensitivity to the active substances, to any of the excipients listed in section 2 Qualitative and Quantitative Composition, 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.

WARNING AND PRECAUTIONS:
Prevenar 13 must not be administered intravascularly.
As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.
This vaccine should not be given as an intramuscular injection to individuals with thrombocytopaenia 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 haematopoietic stem cell transplant 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
The use of pneumococcal conjugate vaccine does not replace the use of 23-valent pneumococcal polysaccharide vaccines in children ≥2 years of age with conditions (such as sickle cell disease, asplenia, HIV infection, chronic illness, or those who are immuno-compromised) placing them at higher risk for invasive disease due to *Streptococcus pneumoniae*. Whenever recommended, children at risk who are ≥24 months of age and already primed with Prevenar 13 should receive 23-valent pneumococcal polysaccharide vaccine.
The potential risk of apnoea and the need for respiratory monitoring for 48-72 h 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. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.
For vaccine serotypes, protection against otitis media is expected to be lower than protection against invasive disease.
Antipyretic treatment should be initiated according to local treatment guidelines for children with seizure disorders or with a prior history of febrile seizures and for all children receiving Prevenar13 simultaneously with vaccines containing whole cell pertussis.

DRUG INTERACTIONS:
Infants and children aged 6 weeks to 5 years: Prevenar 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, varicella and rotavirus vaccine.
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 have been adequately primed with Prevenar 13
Adults aged 50 years and older: Prevenar 13 can be administered concomitantly with trivalent inactivated influenza vaccine (TIV). The immune responses to all four QIV strains were noninferior when Prevenar 13 was given concomitantly with QIV compared to when QIV was given alone.
Different injectable vaccines should always be given at different vaccination sites.

OVERDOSE:
Overdose with Prevenar 13 is unlikely due to its presentations as a pre-filled syringe. However, in infants and children there have been reports of overdose with Prevenar 13 defined as subsequent doses administered closer than recommended to the previous dose. In general, adverse events reported with overdose are consistent with those that have been reported with doses given in the recommended paediatric schedules of Prevenar 13.

ADVERSE REACTION:
- *Infants and children aged 6 weeks to 5 years:* Pyrexia; irritability; any vaccination-site erythema, induration/swelling or pain/tenderness; vaccination-site movement impairment (due to pain), somnolence; poor quality sleep, Vaccination-site erythema or induration/swelling 2.5 cm–7.0
- *Children and adolescents 6 to 17 years of age*: Irritability; any vaccination-site erythema; induration/swelling or pain/tenderness; somnolence; poor quality sleep; vaccination-site tenderness (including impaired movement), Pyrexia
- *Adults ≥18 years and elderly:* Chills; fatigue; vaccination-site erythema; vaccination-site induration/swelling; vaccination-site pain/tenderness (severe vaccination-site pain/tenderness very common in adults aged 18 to 39 years); limitation of arm movement (severe limitation of arm movements very common in adults aged 18 to 39 years). Pyrexia (very common in adults aged 18 to 29 years), Arthralgia; myalgia

PHARMACEUTICAL PRECAUTIONS:
Store refrigerated at 2°C to 8°C. Do not freeze. Discard if the vaccine has been frozen. Store in original package. Keep out of reach of children
During storage, a white deposit and clear supernatant can be observed. This does not constitute a sign of deterioration.
The vaccine is a suspension containing an adjuvant. The vaccine should be shaken well to obtain a homogeneous white suspension and should be inspected visually for any particulate matter and/or variation of physical aspect prior to administration. Do not use if the content appears otherwise.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
Shelf life: 36 months.

REFERENCE: PREVENAR 13® – PNEUMOCOCCAL CONJUGATE VACCINE 13-VALENT (PFS, MDV,SDV) – GDMS version 4.0 (LPDPVR062022)

DATE OF THIS DOCUMENT: 16-FEB-2023