Evimar™ 13

Pneumococcal Polysaccharide
Conjugate Vaccine (Adsorbed) 13 valent BP

Presentation

Evimar™ 13 : Each 0.5 ml dose contains Purified capsular polysaccharides of *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F of 2.6 µg, 2.5 µg, 3.0 µg, 2.5 µg, 2.5 µg, 6.0 µg, 2.85 µg, 2.5 µg, 2.75 µg, 3.25 µg, 2.6 µg, 2.75 µg and 3.0 µg respectively which are individually conjugated to carrier protein tetanus toxoid.

Description: Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) 13 valent BP is a sterile suspension of purified capsular polysaccharides of *Streptococcus pneumoniae* serotypes 1, 3, 4,5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F conjugated to carrier protein tetanus toxoid. The vaccine should be shaken well to obtain a homogeneous milky white suspension. During storage, a white deposit and clear supernatant might be observed due to adjuvant precipitation. The Vaccine is formulated by compounding the capsular polysaccharide antigen of *Streptococcus pneumoniae* serotypes 1,3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F, individually conjugated to tetanus toxoid carrier protein. The individual polysaccharides are extracted from the cultures of *Streptococcus pneumoniae*, and purified through centrifugation, precipitation, and ultrafiltration. The polysaccharides are chemically activated and derivatized, and then conjugated to tetanus toxoid carrier protein to form the glycoconjugate, with aluminum phosphate as the adjuvant.

The vaccine is supplied in a single-dose pre-filled syringe with 0.5 mL suspension for intramuscular injection. Each dose (0.5 mL) of the vaccine contains:

Pneumococcal polysaccharide serotype 1 .....2.6 µg
Pneumococcal polysaccharide serotype 3 .....2.5 µg
Pneumococcal polysaccharide serotype 4 .....3.0 µg
Pneumococcal polysaccharide serotype 5 .....2.5 µg
Pneumococcal polysaccharide serotype 6A .....2.5 µg
Pneumococcal polysaccharide serotype 7F .....2.85 µg
Pneumococcal polysaccharide serotype 9V .....2.5 µg
Pneumococcal polysaccharide serotype 14 .....2.75 µg
Pneumococcal polysaccharide serotype 18C .....3.25 µg
Pneumococcal polysaccharide serotype 19A .....2.6 µg
Pneumococcal polysaccharide serotype 19F .....2.75 µg
Pneumococcal polysaccharide serotype 23F .....3.0 µg
Pneumococcal polysaccharide serotype 6B .....6.0 µg

Excipients: sodium chloride, sodium dihydrogen phosphate, disodium hydrogen phosphate, and aluminum phosphate.

Indications and uses

Evimar 13, is a vaccine indicated for active immunization for the prevention of pneumococcal disease caused by the 13 serotypes contained in the vaccine (1,3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F). The vaccine is indicated for use in infants and children from 6 weeks and adults. The vaccine does not protect against diseases caused by *Streptococcus pneumoniae* serotypes that are not contained in the vaccine.

Dosage and administration

Route of administration: Intramuscular (IM).
Dose: Single dose (0.5 mL).

1.Vaccination Schedule for Infants and Toddlers

Table 1: vaccination schedule for infants 2 months of age

Dose	Dose 1[a,b]	Dose 2[b]	Dose 3[b]	Dose 4[c]
Age at Dose	2 months	4 months	6 months	12-15 months

a *Dose 1 may be given as early as 6 weeks of age.*
b *The recommended dosing interval is 8 weeks.*
c *The fourth dose should be administered at approximately 12-15 months of age.*

Table 2: vaccination schedule for infants 3 months of age

Dose	Dose 1[a]	Dose 2[a]	Dose 3[a]	Dose 4[b]
Age at Dose	3 months	4 months	5 months	12-15 months

a *The recommended dosing interval is 4 weeks.*
b *The fourth dose should be administered at approximately 12-15 months of age.*

2. Vaccination schedule For children 7 months through 5 years of age who have not received the vaccine.

Table 3: For children 7 months through 5 years of age.

Age at First Dose	Total number of 0.5 mL Doses
7-11 months of age	3[a]
12-23 months of age	2[b]
24 months through 5 years of age (prior to the 6th birthday	1

a *The first 2 doses at least 2 months apart; the third dose after the one-year birthday, separated from the second dose by at least 2 months.*
b *Two doses at least 2 months apart.*

3. Vaccination schedule for children from 6 Years, adults and older (>65 years).
A single dose.

Revaccination: Some people with certain medical conditions are also recommended to receive pneumococcal polysaccharide vaccine (PPSV23) 1 year after pneumococcal conjugated vaccine. (minimum interval ≥ 8 weeks)

Method of administration

Since this product is a suspension containing an adjuvant, shake vigorously immediately prior to use to obtain a homogenous, white suspension in the vaccine container. This product is for intramuscular injection only. The preferred sites for injection are the anterolateral aspect of the thigh in infants and the deltoid muscle of the upper arm in toddlers and children. The injection volume is 0.5 mL for each single human dose. The vaccine should not be injected in and/or near the areas where nerve trunks and/or blood vessels may locate.

Contraindications
Hypersensitivity to any component of the product, including active substances, excipients, or tetanus toxoid, etc.

Precautions
1. Do not vaccinate via intravenous route or by gluteal intramuscular injection, and ensure the syringe needle is not puncturing blood vessels during inoculation.
2. Check if the package, container, label, appearance and expiration date of the vaccine are in compliance with corresponding requirements before administration. Do not use the vaccine in case that any crack is observed in the container, loosened stopper, detached label, foreign particle(s) or discoloring inside the container, etc. Do not use the vaccine after the expiration date.
3. Use immediately after unsealing. A single human dose shall be used up each time according to prescribing information.
4. The vaccination should be postponed in case of fever, acute diseases, and acute attack of chronic diseases.
5. Appropriate monitoring and medical care and rescue measures should be readily available in case of occurrence of rare hypersensitivity reactions during vaccination. If allergic reactions occur after vaccination, please go to the vaccination site or hospital in time.
6. Cautions should be taken for vaccination in recipients with thrombocytopenia, any coagulopathy or those who are receiving anticoagulant treatment.
7. Preterm infants should be monitored for the potential risk of apnea during primary series. For preterm infants under hospitalization (gestational age ≤ 30 weeks at birth) vaccinated with PCV13-TT according to the recommended immunization schedule, at least 48 hours of monitoring should be considered. Given the benefit of vaccination in preterm infants, discontinued or deferred vaccination of the product is not recommended.
8. Given that no safety and immunogenicity data are available for PCV3-TT in immunocompromised individuals (e.g., malignancy or nephrotic syndrome), vaccination in this special group should be considered on an individual basis.
9. The use of PCV13-TT does not replace the use of 23-valent Pneumococcal Polysaccharide Vaccine in children ≥ 24 months of age with conditions such as sickle cell disease, asplenia, HIV infection, chronic illness, or those who are immunocompromised.
10. Under no circumstances shall the tetanus toxoid contained in the vaccine replace the routine immunization of tetanus vaccine or tetanus-containing vaccine.
11. This product cannot guarantee all recipients can be protected from any diseases caused by *Streptococcus pneumoniae*.

Co-administration
• No concomitant immunization data are available for the product. During the phase III clinical trial of the product, the interval between vaccination of the product and any other diphtheria, tetanus, and acellular pertussis (DTaP)-containing vaccine was ≥ 10 days. No adverse impact of DTaP-containing vaccine was observed on the immunogenicity of PCV13-TT(13-valent Pneumococcal Polysaccharide Conjugate Vaccine) under the indicated immunization interval.
• Individuals with impaired immune responsiveness due to the use of immunosuppressive therapy (including irradiation, corticosteroids, antimetabolites, alkylating agents, and cytotoxic agents) may not respond optimally to active immunization.

Use in specific populations
Pregnancy:
No data are available for using the product in pregnant women.
Lactation:
Data are not available to assess the effects of the vaccine on the breastfed infant or on milk production/excretion.
Fertility:
No data are available for human subjects for the potential to cause impairment of fertility.

Side effects
The incidence rates of adverse reactions reported in clinical trials, according to the guidance on classifications of adverse events are classified as: very common (≥10%), common (≥1% to <10%), uncommon (≥0.1% to <1%), rare (≥0.01% to <0.1%), and very rare (<0.01%) as follows:

1) Systemic adverse reactions
Very common: fever, diarrhea
Common: crying, cough, nausea/vomiting, fatigue/somnolence, allergic reaction Uncommon: myalgia
2) Local adverse reactions
Very common: redness
Common: swelling, pain, induration
Uncommon: pruritus
Rare: rash (vaccination site)
3) Serious adverse reactions
One case of serious adverse event (SAE) was reported during the primary series in the 3- month age group. This SAE was reported to be fever and considered to be possibly related to the vaccine. Other serious adverse events were adjudicated to be irrelevant to PCV13-TT.

Overdose
Not applicable.

Storage
- Keep out of the reach and sight of children.
- Store at +2ºc to 8ºc. Transportation should also be at +2ºc to +8ºc.
- Do not freeze. Discard vaccine if frozen.
- Protect from light.

Commercial pack
Evimar™13 : Each box contains 0.5 ml of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) 13 valent BP in a pre-filled syringe and 2 needles.

Manufactured by
Incepta Pharmaceuticals Ltd.
Vaccine Division
Savar, Dhaka, Bangladesh
™ Trademark