Summary of Product Characteristics (SmPC)

The summary of product characteristics (SmPC) of Brand name: Prenovax 23 Generic name: Pneumococcal Polysaccharide Vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F) is given below:

1. NAME OF THE MEDICINAL PRODUCT

Prenovax 23 vaccine solution for injection in pre-filled syringe
Pneumococcal Polysaccharide Vaccine 23 serotype

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The 0.5 mL dose of vaccine contains 25 micrograms of each of the following 23 pneumococcal polysaccharide serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F.

3. PHARMACEUTICAL FORM

Solution for injection in pre-filled syringe.
The vaccine is a clear, colorless solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Prenovax 23 vaccine is recommended for active immunization against pneumococcal disease in children aged from 2 years, adolescents and adults.

4.2. Posology and method of administration

The immunization schedules for Prenovax 23 should be based on official recommendations.

Posology

Primary vaccination:

Adults and children of 2 years of age or older- one single dose of 0.5 milliliter by intramuscular or subcutaneous injection. Prenovax 23 vaccine is not recommended for use in children below 2 years of age as the safety and efficacy of the vaccine have not been established and the antibody response may be poor.

Special dosing:

It is recommended that pneumococcal vaccine should preferably be given at least two weeks before elective splenectomy or the initiation of chemotherapy or other immunosuppressive treatment. Vaccination during chemotherapy or radiation therapy should be avoided.

Following completion of chemotherapy and/or radiation therapy for neoplastic disease, immune responses to vaccination may remain diminished. The vaccine should not be administered any sooner than three months after completion of such therapy. A longer delay may be appropriate for patients who have received intensive or prolonged treatment.

Persons with asymptomatic or symptomatic HIV infection should be vaccinated as soon as possible after their diagnosis is confirmed.

Revaccination:

One single dose of 0.5 milliliter by intramuscular or subcutaneous injection.
The specific timing of, and need for, revaccination should be determined on the basis of available official recommendations.

Revaccination at an interval of less than three years is not recommended because of an increased risk of adverse reactions. The rates of local and, in persons aged ≥65 years, some systemic reactions have been shown to be higher after revaccination than after primary vaccination when three to five years have elapsed between doses.

Adults

Healthy adults should not be revaccinated routinely.

Revaccination may be considered for persons at increased risk of serious pneumococcal infection who were given pneumococcal vaccine more than five years earlier or for those known to have a rapid decline in pneumococcal antibody levels. For selected populations (e.g., asplenics) who are known to be at high risk of fatal pneumococcal infections, revaccination at three years may be considered.

Children

Healthy children should not be revaccinated routinely.

Children of 10 years of age and over

May be considered for revaccination according to the adult recommendation.

Children between the ages of 2 and 10 years

Should only be considered for revaccination after 3 years if they are at high risk of pneumococcal infection (e.g., those with nephrotic syndrome, asplenia or sickle cell disease).

Method of administration

A dose of 0.5 mL from a single-dose of PRENOVAX 23 vaccine is to be injected intramuscularly (IM) or subcutaneously (SC).

4.3. Contraindications

This vaccine should not be administered to:

- Individuals with allergic reactions to any component of the vaccine.
- Individuals with fever, acute infection or chronic diseases at the acute stage.
- Individuals with uncontrolled epilepsy or other progressive diseases of the nervous system.
- If only clearly needed, otherwise revaccination within 03 years is not recommended.

4.4. Special warnings and precautions for use

Delay the use of the vaccine in any significant febrile illness, other active infection or when a systemic reaction would pose a significant risk except when this delay may involve even greater risk.

PRENOVAX 23 vaccine should never be injected intravascularly, and precautions should be taken to make sure the needle does not enter a blood vessel. Also, the vaccine should not be injected intradermally, as injection by that route is associated with increased local reactions.

If the vaccine is administered to patients who are immunosuppressed due to either an underlying condition or medical treatment (e.g., immunosuppressive therapy such as cancer chemotherapy or radiation therapy), the expected serum antibody response may not be obtained after a first or second dose. Accordingly, such patients may not be as well protected against pneumococcal disease as immunocompetent individuals.

As with any vaccine, vaccination with PRENOVAX 23 vaccine may not result in complete protection in all recipients.

For patients receiving immunosuppressive therapy, the time to recovery of the immune response varies with the illness and the therapy. Significant improvement in antibody response has been observed for some patients during the two years following the completion of chemotherapy or other immunosuppressive therapy (with or without radiation), particularly as the interval between the end of treatment and pneumococcal vaccination increased.

As with any vaccine, adequate treatment provisions including epinephrine (adrenaline) should be available for immediate use should an acute anaphylactic reaction occur.

Required prophylactic antibiotic therapy against pneumococcal infection should not be stopped after pneumococcal vaccination.

Patients at especially increased risk of serious pneumococcal infection (e.g., asplenics and those who have received immunosuppressive therapy for any reason), should be advised regarding the possible need for early antimicrobial treatment in the event of severe, sudden febrile illness.

Pneumococcal vaccine may not be effective in preventing infection resulting from basilar skull fracture or from external communication with cerebrospinal fluid.

4.5. Interactions with other medicinal products and other forms of interaction

Pneumococcal vaccine can be administered simultaneously with influenza vaccine as long as different needles and injection sites are used.

4.6. Fertility, pregnancy and lactation

Pregnancy

Animal studies are insufficient with respect to effects on reproductive toxicity. The vaccine should not be used during pregnancy unless clearly necessary (the potential benefit must justify any potential risk to the fetus).

Breast-feeding

It is unknown whether this vaccine is excreted in human milk. Caution should be exercised when it is administered to a nursing mother.

Fertility

The vaccine has not been evaluated in fertility studies.

4.7. Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8. Undesirable effects

a. Tabulated list of adverse reactions

The table below summarizes the frequencies of the adverse reactions that were reported with PRENOVAX 23 vaccine in clinical trials and/or post marketing surveillance, using the following convention: 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).

Adverse reactions	**Frequency**
Blood and the lymphatic system disorders	
Haemolytic anaemia Leukocytosis Lymphadenitis Lymphadenopathy Thrombocytopenia	Not known
Immune system disorders	
Anaphylactoid reactions Angioneurotic oedema Serum sickness	Not known
Nervous system disorders	
Febrile convulsions Guillain-Barré Syndrome Headache Paraesthesia Radiculoneuropathy	Not known
Gastrointestinal disorders	
Nausea Vomiting	Not known
Skin and subcutaneous tissue disorders	
Rash Urticaria	Not known
Musculoskeletal and connective tissue disorders	
Arthralgia Arthritis Myalgia	Not known
General disorders and administration site conditions	
Fever (≤38.8°C) Injection site reactions: • erythema • induration • pain • soreness • swelling • warmth	Very common
Injection site cellulitis	Rare

Asthenia Chills Fever Injected limb mobility decreased Malaise Peripheral oedema	Not known
Investigations	
C-reactive protein increased	Not known

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: pneumococcal vaccines, pneumococcus, purified polysaccharides antigen.

The vaccine is prepared from purified pneumococcal capsular polysaccharide antigens derived from the 23 serotypes that account for approximately 90% of invasive pneumococcal disease types. The following pneumococcal capsular polysaccharides are included: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F.

Immunogenicity

The presence of type-specific humoral antibodies is generally thought to be effective in preventing pneumococcal disease. A ≥2-fold increase in antibody level following vaccination was associated with efficacy in clinical trials of polyvalent pneumococcal polysaccharide vaccines. However, the concentration of anti-capsular antibody required to protect against pneumococcal infection caused by any specific capsular type has not been established. Most persons aged ≥2 years (85 to 95%) respond to vaccination by making antibody to most or all of the 23 pneumococcal polysaccharides in the vaccine. Bacterial capsular polysaccharides induce antibodies primarily by T-cell-independent mechanisms and elicit poor or inconsistent antibody responses in children aged <2 years.

Antibodies can be detected by the third week following vaccination but may decline as soon as 3 to 5 years after vaccination and a more rapid decline may occur in some groups (e.g., children and the elderly).

Immune responses to eight of the polysaccharides in PRENOVAX 23 vaccine have been compared following administration of a single dose of vaccine or placebo. Four groups of subjects were entered as defined by age (50-64 years and ≥65 years) and by prior vaccination status (no prior vaccination or 1 vaccination 3-5 years previously).

- Prior to vaccination, antibody levels were higher in the revaccination group than in the primary vaccination group.
- In the primary and revaccination groups the geometric mean antibody levels for each serotype increased from pre- to post-vaccination.
- The ratios in geometric mean antibody concentrations by serotype at day 30 between those who were revaccinated and those who were given primary vaccination ranged from 0.60-0.94 in the ≥65 years group and from 0.62-0.97 for the group aged between 50-64 years.

The clinical relevance of the lower antibody responses observed on revaccination compared to primary vaccination is not known.

Efficacy

The efficacy of polyvalent Pneumococcal polysaccharide vaccine was established for pneumococcal pneumonia and bacteraemia in randomised controlled trials that were conducted among novice gold miners in South Africa. The protective efficacy against pneumococcal pneumonia, the primary endpoint in these studies, was 76.1% with a 6-valent vaccine and 91.7% with a 12-valent preparation. In trials conducted in populations for which the vaccine is indicated (see section 4.1), vaccine effectiveness was reported to be 50 to 70% (e.g., persons with diabetes mellitus, chronic cardiac or pulmonary disease, and anatomic asplenia).

One study found that vaccination was significantly protective against invasive pneumococcal disease caused by several individual serotypes (e.g., 1, 3, 4, 8, 9V, and 14). For other serotypes, the number of cases detected in this study were too small to draw conclusions about serotype specific protection.

The results from one epidemiologic study suggest that vaccination may provide protection for at least 9 years after receipt of the initial dose of vaccine. Decreasing estimates of effectiveness have been reported with increasing interval after vaccination, particularly among the very elderly (persons aged ≥85 years).

The vaccine is not effective for the prevention of acute otitis media, sinusitis and other common upper respiratory tract infections.

5.2. Pharmacokinetic properties

Since PRENOVAX 23 is a vaccine, pharmacokinetic studies were not performed.

5.3. Preclinical safety data

No preclinical safety testing was performed using the vaccine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium chloride
Sodium dihydrogen phosphate
Disodium hydrogen phosphate
Water For injection

6.2. Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store in a refrigerator ($2^oC – 8^oC$).
Do not freeze.

6.5. Nature and contents of container

1 Prefilled Syringe and two needles in one box.

6.6. Special precautions for disposal and other handling

The normal appearance of the vaccine is a clear, colorless solution. Parenteral products should be inspected visually for extraneous particulate matter and/or discoloration prior to administration.

In the event of either being observed, discard the medicinal product.
The vaccine should be used directly as supplied; no dilution or reconstitution is necessary.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Incepta Vaccine Limited
Dewan Idris Road, Bara Rangamatia, Zirabo, Savar Dhaka, Bangladesh.

8. MARKETING AUTHORISATION NUMBER(S)

363-42-069

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 09.06.2022
Date of latest renewal: N/A

10. DATE OF REVISION OF THE TEXT

28 June 2022