SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medical Product

Prenovax 23

Sterile liquid vaccine for injection in Prefilled Syringe, 0.5 ml

Pneumococcal Polysaccharide Vaccine 23 valent BP

2. Qualitative and quantitative composition

Each 0.5 ml contains Pneumococcal Polysaccharide Vaccine 23 valent BP consisting of purified capsular polysaccharides of Streptococcus pneumoniae serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F and 33F of 25 µg each.

Prenovax 23 is a sterile liquid vaccine consisting of a mixture of purified capsular polysaccharides from Streptococcus pneumoniae serotypes (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F and 33F). No preservatives are added. This vaccine is supplied as a single-dose, pre-filled syringe. This vaccine is presented as a clear and colorless solution.

EXCIPIENTS: Sodium chloride Sodium dihydrogen phosphate Disodium hydrogen phosphate Water For lnjection

3. Pharmaceutical form

This vaccine is presented as a clear and colorless solution.

4. Clinical Particulars

4.1 Therapeutic indications

Prenovax 23 is a vaccine indicated for active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A,

12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F). Prenovax 23 is approved for use in persons 50 years of age or older and persons aged ≥ 2 years who are at increased risk for pneumococcal disease.

4.2 Posology and method of administration

4.2.1 Posology

Dose: Single dose (0.5 mL).

This vaccine is for intramuscular or subcutaneous injection (intramuscularly recommended) and the preferred administration site is the deltoid muscle of the lateral upper arm or lateral mid thigh. Intravascular and intradermal injection is prohibited.

Revaccination:

Persons at high risk (splenectomy) who were previously vaccinated over 5 years or with significant decreasing antibody titers (e.g., nephrotic syndrome, renal failure and organ transplantation) are recommended to revaccinate against pneumococcal diseases.

Children under 10 years old with nephrotic syndrome, splenectomy or sickle cell diseases are recommended to revaccinate 3-5 years later after the initial vaccination.

The immune persistence of this product has so far not demonstrated by any clinical study. The recommendations for revaccination above are compiled based on the recommendations for subsequent doses prescribed in the Prevention of Pneumococcal Diseases-Recommendations by the Advisory Committee on Immunization Practices.

4.2.2 Method of administration

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. If either of these two conditions exists, the vaccine should not be administered.
- Do not mix Prenovax 23 with other vaccines in the same syringe or vial.
- Use a separate sterile syringe and needle for each individual patient to prevent transmission of infectious agents from one person to another.
- Administer Prenovax 23 intramuscularly or subcutaneously into the deltoid muscle or lateral mid-thigh. Do not inject intravascularly or intradermally.

4.3 Contraindication

This vaccine should not be administered to:

- Individuals with allergic reactions to any component of the vaccine.
- Individuals with encephalopathy, uncontrolled epilepsy, or other progressive diseases of the nervous system.
- Individuals with fever, acute infection, or chronic diseases at the acute stage.
- Only if clearly needed, otherwise revaccination within 3 years is not recommended.

4.4 Special warnings and precautions for use

- Do not administer intracutaneously or intravenously, and ensure the syringe needle is not puncturing blood vessels during inoculation.
- The vaccine shall be administered with caution to nursing women or individuals with family or individual history of convulsion, history of epilepsy and allergic diathesis.
- Check if the package, container, label, appearance and expiration date of the vaccine follow corresponding requirements before administration. Do not use the vaccine in case that any crack is observed in the container, loosened stopper, detached label, particulate matter or discoloring inside the container, etc. Do not use the vaccine after the expiration date.
- Use immediately after unsealing. A single human dose shall be used up each time according to prescribed information.

- Appropriate monitoring, medical care and rescue measures should be readily available in case of rare hypersensitivity reactions during vaccination. The recipient shall be observed for at least 30 minutes on site following injection.
- If allergic reactions occur after vaccination, please visit the vaccination site or hospital in time.
- Do not freeze. Discard the vaccine if it has been frozen.
- Defer vaccination in persons with moderate or severe acute illness.
- Caution and appropriate care should be exercised in administering vaccine to individuals with severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.
- This vaccine does not replace the need for penicillin (or other antibiotic) prophylaxis against pneumococcal infection. In patients who require penicillin (or other antibiotic) prophylaxis against pneumococcal infection, such prophylaxis should not be discontinued after vaccination.
- Persons who are immunocompromised, including persons receiving immunosuppressive therapy, may have a diminished immune response.
- The vaccine may not be effective in preventing pneumococcal meningitis in patients who have chronic cerebrospinal fluid (CSF) leakage resulting from congenital lesions, skull fractures, or neurosurgical procedures.

4.5 Interaction with other medical products and forms of interaction

- As per the information available for other similar marketed vaccines, it may be administered at the same time with influenza vaccine by separate injection in the other arm.
- Consider administration of the live vaccines separated by at least 4 weeks.
- Any medications, being or having recently been administered, including OTCs, should be reported to the physician.

4.6 Pregnancy and lactation

4.6.1 Pediatric Use

The vaccine is not approved for use in children less than 2 years of age. Children in this age group do not develop an effective immune response to the capsular types contained in this polysaccharide vaccine.

The ACIP has recommendations for use of this vaccine in children 2 years of age or older, who have previously received pneumococcal vaccines, and who are at increased risk for pneumococcal disease.

4.6.2 Pregnancy

Administering this vaccine in pregnant women is not recommended. Administration of the vaccine in this population is determined by doctors based on the risk faced with the potential recipients.

4.6.3 Breast-feeding

Administration of the vaccine in nursing mothers should be determined by doctors with cautions.

4.6.4 Fertility

No fertility data are available

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use machines have been performed. However, some of the effects mentioned under section 4.8 “Undesirable effects” may temporarily affect the ability to drive or use machines

4.8 Undesirable effects

The most common adverse reactions: injection-site pain/soreness/tenderness, injection-site swelling/induration, headache, injection-site erythema, asthenia/fatigue and myalgia.

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:

4.8.1 Very common:

- Local reaction(s): pain.

4.8.2 Common:

- Local reactions: redness, swelling, itching.
- Systemic reactions: fever, fatigue, headache,

4.8.3 Uncommon:

- Local reaction(s): induration.
- Systemic reactions: vomiting, rash, allergy.

4.9 Overdose

Not applicable

5. Pharmacological properties

5.1 Pharmacodynamic properties

5.1.1 Pharmacotherapeutic group:

Vaccines, Pneumococcal polysaccharide vaccines

5.1.2 Mechanism of action

It has been established that the purified pneumococcal capsular polysaccharides induce antibody production and that such antibody is effective in preventing pneumococcal disease. Clinical studies have demonstrated the immunogenicity of each of the 23 capsular types when tested in polyvalent vaccines. Protective capsular type-specific antibody levels generally develop by the third week following vaccination. Bacterial capsular polysaccharides induce antibodies primarily by T-cell-independent mechanisms. Therefore, antibody response to most pneumococcal capsular types is generally poor or inconsistent in children aged < 2 years whose immune systems are immature.

5.2 Pharmacokinetic properties

Not applicable to vaccine products.

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

2 years

6.4 Special precautions for storage

- Keep out of the reach and sight of children
- Store and transport at +2 ^{O}C to +8 ^{O}C
- Protect from light

6.5 Nature and contents of container

- Pre-filled syringe 0.5 ml of suspension in a pre-filled syringe (type I glass) with a plunger stopper (rubber butyl) without needles.
- Pack sizes of 1 pre-filled syringes without needles

6.6 Special precautions for disposal and other handling

The content of the syringe should be inspected visually both before and after shaking for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either being observed, discard the vaccine. The vaccine should be well shaken before use. The prefilled syringe is for single use only. Inject the entire contents of the syringe.

7. Marketing authorization holder

Incepta Pharmaceuticals Ltd.

Vaccine Division
Savar, Dhaka
Bangladesh

8. Drug authorization number(s)

Prenovax 23 0.5 ml PFS- 363- 42-069

9. Date of first authorization /renewal of the authorization

June, 2022

10. Date of revision of the text

June, 2027