Summary of Product Characteristics for Pharmaceutical Products

1. Name of the Medicinal Product

23-Valent Pneumococcal Polysaccharide Vaccine

2. Qualitative and Quantitative Composition

The product is a polysaccharide vaccine produced through culture and purification by using 23 most common and invasive serotypes of S. pneumonia, including 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F and 33F. The finished product is a colorless and transparent injection liquid.

The single dose of 0.5ml final product is composed of:
23 serotypes of pneumococcal capsular polysaccharide: 25μg/dose/serotype
Phenol: 1.25mg
Sodium Chloride: 4.15mg
Anhydrous Disodium hydrogen phosphate: 65μg
Sodium dihydrogen Phosphate: 26.5μg

3. Pharmaceutical Form

0.5ml/dose/syringe, injection

4. Clinical Particulars

4.1 Therapeutic indication

23-valent pneumococcal polysaccharide vaccine consists of 23 serotypes of pneumococcal polysaccharide antigen which can induce body humoral immunity to protect from pneumococcal infectious disease caused by the most common 23 kinds of pneumococcal serotypes. Its immunization coverage accounts for 90% serotypes causing pneumococcal infections. The vaccine could be used for the prevention of pneumonia, meningitis, otitis media and bacteremia and other diseases caused by pneumococcal serotypes contained in the vaccine. This vaccine has no immune effect to the pneumococcal serotypes which are not contained in the vaccine.

4.2 Administration and dosage

(1) Vaccination site and route: intramuscular or subcutaneous injection at the deltoid muscle of the upper arm (intramuscular injection is recommended).
(2) Vaccination schedule and dosage: one dose per injection, 0.5ml/dose.
(3) Booster vaccination: booster vaccination is not recommended for populations with normal immune functions and have been vaccinated with 23-valent pneumococcal polysaccharide vaccine. For high-risk groups to pneumococcal infection (such as populations received splenectomy) who have been administered with this vaccine over 5 years, or whose antibody titer has decreased significantly (such as populations

with nephrotic syndrome, renal failure or organ transplantation), booster vaccination is recommended. If booster vaccination is needed, inject 1 dose, 0.5ml/dose.

4.3 Contraindication

Subjects with known allergic reactions to any components of the vaccine are forbidden to use this product.

4.4 Precautions

(1) Intravenous and intradermal injection is forbidden for this product. Ensure the needle does not penetrate into the blood vessel;
(2) Do not use the vaccine if the vaccine appears turbid, contains foreign matters, with cracks on the pre-filled syringe or rubber piston loose, or expired etc.
(3) With the vaccine, the expected antibody response in serum may not be elicited for patients receiving immunosuppressive therapy.
(4) Patient with severe heart or lung disease should use this vaccine with extreme caution and be closely monitored for systemic adverse reactions.
(5) Patient with any febrile respiratory diseases or other active infections should delay administration of the vaccine, unless the doctor considers it would be more risky without vaccination.
(6) Once the vaccine is opened, it should be used immediately and used up once following the specified dosage/person.
(7) Epinephrine and other drugs shall be prepared for first aid in case of occasional severe allergic reaction. Recipients of the vaccine should observe on site for at least 30 minutes after injection.
(8) Freezing of the vaccine is strictly prohibited.

4.5 Drug Interaction

(1) At present, clinical data on concomitant administration with other vaccines are unavailable. But referring to similar vaccines marketed, the 23-valent pneumococcal polysaccharide vaccine can be administered with influenza vaccine during the same visit at separate sites..
(2) If any other vaccine or drug is using or has been used recently, it is recommended to consult a professional physician before vaccination to avoid possible drug interaction.

4.6 Pregnancy and lactation

This vaccine is not recommended for pregnant women. If vaccination is needed, the physician shall make the decision based on risk status.
Lactating women should administer with caution.
Pediatric use
The vaccine is not recommended for children under 2 years old.

4.7 Effect on ability to drive and machine

N/A

4.8 Undesirable effects

a. Summary of the safety profile

Analysis according to the adverse reactions response shows that most reactions are local reactions and mild fever and can be relieved spontaneously and the adverse reaction rate is low. This indicates the 23-Valent Pneumococcal Polysaccharide Vaccine has good safety.

b. Tabulated list of adverse reactions

Common adverse reactions:	Mild reactions such as transient pain, red and swelling, induration at the injection site or transient fever may occur, normally which can be relieved spontaneously. Symptomatic treatment may adopt if necessary.
Rare adverse reactions:	Rare adverse reactions include headaches, discomfort, weakness, lymphadenitis, anaphylaxis, serum sickness, arthralgia, myalgia, rash, and urticaria.
Extremely rare adverse reactions:	Patients with stable idiopathic thrombocytopenic purpura may have extremely low chances of thrombopenia recurrence between 2-14 days after vaccination; the thrombopenia may last for 2 weeks. Among the populations receiving pneumococcal vaccine, neurological abnormalities cases such as paresthesia, acute radiculopathy were rarely reported, and it's causation with the vaccine is not confirmed yet.
Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the PPB website https://pv.pharmacyboardkenya.org.	

4.9 Overdose

N/A

5. Pharmaceutical properties

5.1 Pharmacodynamics properties

N/A

5.2 Pharmacokinetics properties

N/A

5.3 Preclinical safety data

Acute Toxicity test:

Test product: 23-Valent Pneumococcal Polysaccharide Vaccine

Control product: 0.5ml saline
Test animal: NIH mice
The mice are injected with 23-Valent Pneumococcal Polysaccharide Vaccine (28.75mg/100g, 43.13mg/100g) respectively. Within 14 days, all the mice in each test group survived without any abnormal reaction and the weight gained.
Allergen test:

Test product: 23-Valent Pneumococcal Polysaccharide Vaccine
Positive control: Fetal bovine serum
Negative control: Distilled water
Test animal: Guinea pig
The 23-Valent Pneumococcal Polysaccharide Vaccine allergen tests results are all met the standard.

6. Pharmaceutical particulars

6.1 List of excipients

Excipients	Phenol
	Sodium chloride
	Anhydrous disodium hydrogen phosphate
	Sodium dihydrogen phosphate

6.2 Compatibilities

Our company entrusted Sichuan Institute for Drug Control to conduct compatibility study for the first three consecutive validation batches of the product with the prefilled syringe assemblies (borosilicate glass tube (with injection needle) of the prefilled syringe, polyisoprene rubber needle cap and brominated butyl rubber plunger). The study includes extraction test with blank packaging material, migration test at accelerated condition (25±2℃, upward and inverted) and long-term condition (2-8℃, upward and inverted), as well as glass tube delamination. So far, compatibility studies at accelerated condition for 6 months and long-term condition for 24 months have been completed. Existing data showed that during 24-month study at long-term condition, the prefilled syringe assemblies have good compatibility with the vaccine.

6.3 Shelf life

24 months

6.4 Special precaution for storage

The product should be stored and shipped at 2~8℃, protected from light.

6.5 Nature and content of container

Brominated butyl rubber plunger for pre-filled syringes and pre-filled syringe assemblies (with needle, cap and glass tube)

6.6 Special precautions for disposal and other handling

Refer to the section 4.4

7. Marketing authorization holder

Chengdu Institute of Biological Products Co., Ltd.
Address: 379#, 3rd Section, Jinhua Road, Jinjiang District, Chengdu, Sichuan

8. Marketing authorization number(s)

H2023/CTD9832/22607

9. Date of first authorization/renewal of the authorization

Year of first authorization: 2006
Date of latest renewal of the authorization: October 27th, 2020

10. Date of revision of the text

July 1st, 2022