**Proposed artwork**

_Shan6_ 0.5mL_Pack Insert-WHO_PO

**English**

Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), _Haemophilus influenzae Type b Conjugate and Poliomyelitis (Inactivated Vaccine) (Adsorbed)**

**COMPOSITION**

_Shan6_ is an adsorbed tetavalent liquid combination vaccine composed of Diphtheria Toxoid, Tetanus Toxoid, _Haemophilus influenzae Type b_ conjugate and Poliomyelitis vaccine. The vaccine is intended for use in pediatric populations. The vaccine is delivered as a series of injections (0.5 mL each) to be administered in children aged between 24 months and 13 years.

**Potential Adverse Events**

Adverse events that have been reported with other vaccines containing one or more of the components of this vaccine include:

- **Diphtheria toxoid:**
  - **Local:** Injection-site reactions, including pain, swelling, and erythema.
  - **Systemic:** Fever, malaise, and headache.

- **Tetanus toxoid:**
  - **Local:** Injection-site reactions, including pain, swelling, and erythema.

- **Pertussis antigens** (whole cell or acellular pertussis vaccines):
  - **Local:** Injection-site reactions, including pain, swelling, and erythema.
  - **Systemic:** Irritability, sneezing, coughing, and respiratory distress.

- **Hepatitis B surface antigen (rDNA):**
  - **Local:** Injection-site reactions, including pain, swelling, and erythema.
  - **Systemic:** Headache, nausea, and vomiting.

- **Haemophilus influenzae type b conjugate vaccine:***
  - **Local:** Injection-site reactions, including pain, swelling, and erythema.
  - **Systemic:** Fever, irritability, and respiratory symptoms.

- **Poliovirus (inactivated):**
  - **Local:** Injection-site reactions, including pain, swelling, and erythema.
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**ADVERSE REACTIONS**

_Vaccine Vial Monitors (VVM)_ are on the label of vaccine supplied through Sanofi Pasteur. The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the circle, then the vaccine is acceptable.

**POSSIBLE MYOCRHEUM**

**Antibody Titers:**

Antibody titers should be considered in the evaluation of the clinical significance of adverse events related to vaccinations.

**CONTRAINdications:**

- History of severe allergic reaction to any component of the vaccine.

**SPECIAL POPULATIONS**

- Pregnant women:
  - Vaccination may be delayed until the end of pregnancy.
  - Vaccination may be indicated during pregnancy if the vaccine is recommended by local authorities.

- Immunocompromised patients:
  - Vaccination may be delayed until the end of chemotherapy or immunosuppressive treatment.

- Immunocompetent patients:
  - Vaccination may be given as per the routine immunization schedule.

**ADDITIONAL INFORMATION**

- **Distribution:**
  - **Vaccines:** Distributed in a cold chain.
  - **Vaccine Vial Monitors (VVM):** Distributed in a warm chain.

- **Storage:**
  - **Vaccines:** Store at +2°C to +8°C.
  - **Vaccine Vial Monitors (VVM):** Store at room temperature.

- **Handling:**
  - **Vaccines:** Handle as per good laboratory practice.
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- **Disposal:**
  - **Vaccines:** Dispose of according to locally agreed procedures.
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- **Use:**
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**PRECAUTIONS:**

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