Abridged Prescribing Information
For the use of a Registered Medical Practitioner

Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and *Haemophilus influenzae* Type b Conjugate Vaccine (Adsorbed) I.P.

Shan 5®

COMPOSITION

The active substances are:
Each dose of 0.5 mL contain:

Diphtheria Toxoid……..…….……..	≥ 30 IU
Tetanus Toxoid ……...……..…….	≥ 60 IU
B. pertussis (whole cell)…… ……	≥ 4 IU
rDNA Hepatitis B Surface Antigen...…….…	10 µg
Purified capsular polysaccharide of Hib…. conjugated to 20 – 40 mcg of Tetanus Toxoid (carrier protein)	10 µg

The other components are: thiomersal as preservative, aluminium phosphate gel equivalent to Al^{+++} as adjuvant, sodium chloride as tonicity modifiers, acetic acid and/or sodium hydroxide for pH adjustment and water for injection.

THERAPEUTIC INDICATIONS

SHAN 5® is indicated for active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis B and *Haemophilus influenzae* type b in infants starting from 6 weeks of age. The vaccine should not be used as a birth dose vaccine.

CONTRAINDICATIONS

Shan 5 should not be administered to subjects with either known hypersensitivity to any component of the vaccine, or having shown signs of hypersensitivity after previous administration of **Shan 5** or Diphtheria, Tetanus, Pertussis, Hepatitis B or Hib vaccines. It is a contraindication to administer the vaccine in the presence of any evolving or suspected neurological condition.

As with other vaccines, the administration of **Shan 5** should be postponed in subjects suffering from acute severe febrile illness. However, the presence of minor illnesses such as mild upper respiratory infections with or without low grade fever is not a contraindication for further use.

Shan 5 is contra-indicated if the child has experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with pertussis containing vaccine or any progressive neurological disorder. In these circumstances the vaccination may be continued with DT, Hib and Hepatitis B vaccines after a thorough medical evaluation and assessment of risk benefit.

WARNING AND PRECAUTIONS

Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and the possible occurrence of undesirable events) and a clinical examination.

If any of the following events occur in temporal relation to receipt of **Shan 5**, the decision to give subsequent doses of **Shan 5** or any other vaccine containing the pertussis component should be carefully considered.

- Temperature of ≥39.5º C (103.1°F) within 48 hours, not due to another identifiable cause;
- Inconsolable crying lasting ≥ 3 hours, occurring within 48 hours;
- Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours;
- Convulsions/Seizures with or without fever, occurring within 3 days.

There may be circumstances, such as presence of high fever, when the potential benefits of the vaccine use outweigh possible risks.

HIV infection is not considered as a contraindication for Diphtheria, Tetanus, Pertussis, Hib and Hepatitis B vaccination. The expected immunological response may not be obtained after vaccination of immunosuppressed patients, for example, patients on immunosuppressive therapy including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses). Vaccine should be administered to prevent the child from contacting the diseases should be undertaken as per recommended standard schedules.

As with all injectable vaccines, appropriate medical treatment should always be readily available in case of anaphylactic reactions following the administration of the vaccine. For this reason, the vaccinee should remain under medical supervision for atleast 30 minutes after vaccination. Adrenaline injection (1:1000) must be immediately available should an acute anaphylactic reaction occur due to any component of the vaccine. For treatment of severe anaphylaxis the initial dose of adrenaline is 0.1- 0.5 mg (0.1-0.5ml of 1:1000 injection) given subcutaneously or intramuscularly. For infants the recommended dose of adrenaline is 0.01mg/kg (0.01ml/kg of 1:1000 injection). Single pediatric dose should not be more than 0.5mg (0.5 ml). Post vaccination with injectable vaccines, it is expected that there may be minor swelling, tenderness and redness at the injection site. In case this does not resolve within seven days or if associated with any increase in severity, it should be brought to the physician's notice immediately for further treatment and care.

Shan 5 should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects, unless the potential benefit clearly outweighs the risk of administration.

DOSAGE AND ADMINISTRATION

The recommended single human dose of the vaccine is 0.5 mL. The primary vaccination schedule consists of three doses administered at an interval of atleast 4 weeks between doses and starting at 6 weeks of age. In geographical areas where there is a high endemicity of Hepatitis B and significant perinatal transmission, the practice to administer monovalent Hepatitis B vaccine at birth should be continued. Three doses of the pentavalent vaccine can be used to complete the primary series starting from 6 weeks of age.

Method of administration

The liquid vaccine in the vial should be shaken before use to homogenize the suspension. The vaccine should be injected deep intramuscularly. Do not inject subcutaneously or intravenously. The anterolateral aspect of the upper thigh is the preferred site of injection. An injection into a child's buttocks may cause injury to the sciatic nerve and is not recommended. The vaccine must not be injected into the skin as this may give rise to local reactions. A sterile syringe and sterile needle must be used for the injection. Another injectable vaccine if co-administered with **Shan 5** should be administered at a different anatomical site. The vaccine should be visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed discard the vaccine. **Shan 5** should not be mixed with any other vaccine or injectable in the same syringe before administration.

Once opened multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and *Haemophilus influenzae* Type b Conjugate Vaccine (Adsorbed) I.P. from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for upto a maximum of 4 weeks, provided that all of the following conditions are met:

- The expiry date has not passed.
- The vaccines are stored under appropriate cold chain conditions.
- The vaccine vial septum has not been submerged in water.
- Aseptic technique has been used to withdrawal doses.

SAFETY RELATED INFORMATION

In a Phase III study designed to evaluate immune lot consistency and immune non inferiority of **Shan 5** as compared to a licensed pentavalent vaccine, conducted at eleven centers across India, 1100 subjects (15 toddlers and 1085 infants) were vaccinated. The study demonstrated seroprotection rates for Hib (99.5%), Hepatitis B (97.8%), Diphtheria (100%), Tetanus (100%) and seroresponse rate of 70.1% for whole cell Pertussis component of **Shan 5** vaccine as evaluated after a three dose primary series administered at 6-8, 10-12 and 14-16 weeks of age. The seroprotection/ seroresponse rates were statistically non inferior to the licensed comparator pentavalent vaccine for all five antigens. The solicited and unsolicited local and systemic adverse events were comparable between **Shan 5** and

comparator groups and **Shan 5** was considered as safe and well tolerated in the study age group.

Adverse Reactions

In a Phase III study conducted on **Shan 5**, most commonly reported local adverse events were pain, redness and swelling at injection site. Among the systemic reactions fever, vomiting, crying, drowsiness, loss of appetite and irritability were commonly observed. All the events were resolved without any sequelae within 7 days post administration of vaccine. All the events were mild to moderate in severity. Rarely a nodule may be palpable at the injection site for few weeks, which disappear with or without medication. The frequency and severity of local and systemic reactions observed in the phase III study was comparable between **Shan 5** and the licensed pentavalent vaccine.

For full prescribing information, please contact Sanofi Pasteur India Pvt. Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai-400072.

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