

For the use of Registered Medical Practitioners or hospital or laboratory only.

Adsorbed Diphtheria, Tetanus, Pertussis, Hepatitis-B (r-DNA) & Haemophilus influenzae Type b conjugate Vaccine

Shan5

Prescribing Information:

Qualitative and Quantitative Composition:

Shan5 contains diphtheria (D), tetanus (T) toxoids, inactivated pertussis bacteria (Pw), purified major surface antigen of the hepatitis B virus (HBV), adsorbed on aluminium salts and conjugated *Haemophilus influenzae* type b polysaccharide.

The D and T toxoids are prepared from the toxins of cultures of *Corynebacterium diphtheriae* and *Clostridium tetani* by formalin inactivation using established technology. The Pw component is obtained by heat inactivation of phase I culture of *Bordetella pertussis* bacteria.

The surface antigen of the HBV (HBsAg) is produced from genetically-engineered yeast cells (*Pichia pastoris*) which carry the gene coding for the major surface antigen of the HBV. This HBsAg expressed in yeast cells is purified by several physico-chemical steps.

The capsular polysaccharide is produced from cultures of *Haemophilus influenzae* type b and purified. Purified polysaccharide (PRP) is covalently bound to tetanus toxoid (T) to produce PRP-T conjugate.

Each dose 0.5 mL contains:

Active Ingredients:

Diphtheria toxoid	≥ 30 IU [25 Lf]
Tetanus toxoid	≥ 60 IU [5Lf]
B. Pertussis (Whole cell)	≥ 4 IU [15 IOU]
Purified Hepatitis-B surface antigen	10 mcg
Purified capsular polysaccharide of HB covalently bound to 20-40 microgram of Tetanus toxoid [PRP-T]	10 mcg

Excipients:

Thiomersal	≤ 0.050 mg
Aluminium Phosphate equivalent to Al ⁺⁺⁺	0.625 mg
Sodium Chloride	4.5 mg
Water for Injection	q.s. to 0.5 mL

Therapeutic Indications:

Shan5 is indicated for active immunization against diphtheria, tetanus, pertussis, hepatitis B (HB) and *Haemophilus influenzae* type b in infants from 6 weeks of age.

Posology:

The recommended dose (0.5ml) of the vaccine must be administered. The primary vaccination schedule consists of three doses within the first six months of life. Where HB vaccine is not given at birth, the combined vaccine can be administered beginning as early as 6 weeks of age. Where there is a high endemicity of HB, the practice to administer HB vaccine at birth should be continued. Three vaccine doses must be administered at intervals of at least 4 weeks.

In the case of children born to known HB carrier mothers, the immunoprophylactic measures for hepatitis B should not be modified. This may require separate vaccination with HB and DTPw vaccines and also include the administration of HBIG at birth.

Method of Administration:

Shan5 is for deep intramuscular injection, preferably in the anterolateral thigh. It is recommended that in patients with thrombocytopenia or bleeding disorders, the vaccine be administered subcutaneously.

Contra-indications:

Shan5 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 diphtheria, tetanus, pertussis, HB or HB vaccines.

As with other vaccines, the administration of **Shan5** should be postponed in subjects suffering from acute severe febrile illness.

Shan5 is contra-indicated if the child has experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with pertussis containing vaccine. In these circumstances the vaccination course should be continued with DT and HB vaccines.

Special 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 **Shan5**, the decision to give subsequent doses of vaccine containing the pertussis component should be carefully considered.

- Temperature of ≥40° C within 48 hours, not due to another identifiable cause;
- Collapse or shock-like state (hypotonic-hyporeponsive episode) within 48 hours;
- Persistent crying lasting ≥3 hours, occurring within 48 hours;
- Convulsions with or without fever, occurring within 3 days.

There may be circumstances, such as a high incidence of pertussis, when the potential benefits of the vaccine use outweigh possible risks.

A history of febrile convulsions, a family history of convulsions, SIDS (Sudden Infant Death Syndrome) or of any adverse event following **Shan5** vaccination does not constitute contraindications. HIV infection is not considered as a contraindication for diphtheria, tetanus, pertussis and HB vaccination. The expected immunological response may not be obtained after vaccination of immunosuppressed patients, for example, patients on immunosuppressive therapy.

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 30 minutes after vaccination.

Shan5 should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Shan5 should under no circumstances be administered intravenously.

Pregnancy and lactation:

As **Shan5** is not intended for use in adults, information on the safety of the vaccine when used during pregnancy or lactation is not available.

Clinical Experience:

In a phase III study conducted at ten centers across India, 365 infants were vaccinated in a three-dose EPI schedule with either **Shan5** or the competitor vaccines. The results of this study revealed no significant difference in the seroconversion rates between **Shan5** and the competitor vaccines for all the five components. A total of 98.32% of the infants in **Shan5** group were protected against *Haemophilus influenzae* type b as compared to 100% and 98.94% infants in the competitor vaccines group A and B. Seroconversion rates to other vaccine components in **Shan5** group namely Hepatitis B, Diphtheria and Tetanus were 97.77 %, 99.44% and 99.44% respectively. Similar immune responses were observed with both the comparators. Overall 89.94% of infants in the **Shan5** group responded to pertussis component as compared to 92.39% in competitor A and 76.6% in competitor B groups. The Geometric Mean Titres (GMTs) of all the five components for **Shan5** and the two competitor vaccines were comparable 3-4 weeks after the last dose of vaccines. The most commonly reported adverse event in all the vaccine groups were mild pain and mild swelling at the injection site. The incidence rates of the adverse events in all the vaccine groups were comparable. No previously unreported adverse events were observed during the course of the trial. **Shan5** was found to be safe and efficacious in infants when administered in a three-dose EPI schedule.

Presentation:

0.5 mL single dose vial.

Shelf-life:

The expiry date of the vaccine is indicated on the label and packaging.

Special precautions for storage:

Shan 5 should be stored at +2°C to +8°C. Do not freeze. Discard vaccine if frozen.

Instruction for use/handling:

How to use Shan5

Shan5 is presented as suspension. Upon storage, a white deposit and clear supernatant may be observed. The vaccine should be shaken well in order to obtain a homogeneous turbid white suspension and visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either of the above being observed, discard the vaccine.

Developed, Manufactured and Marketed by:

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Ref:

1. Data on file, Shantha Biotechnics Ltd.

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Folding: 18 mm

Artwork No.	SBL/PL-DOM-Eng-LT/ 1.1- T 0.5 11.2007
Category	Vaccine
Pharmacopiea	DOM
Domestic	India
Language	English
Dimensions:	80 x 144 mm

Colours	CMYK C 100 M80 Y0 K0
Department	Approved by
Production	
Quality Control	
Regulatory Affairs	A member of
Quality Assurance	
Marketing	France