

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

Rx

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

Shan 5[®]

(Diphtheria, Tetanus, whole cell Pertussis, Hepatitis B and Haemophilus influenzae type b conjugate Vaccine)

Prescribing Information

Qualitative and Quantitative Composition

Shan 5[®] contains Diphtheria (D) Toxoid, Tetanus (T) Toxoid and purified major surface antigen of the Hepatitis B virus (HBV), adsorbed on Aluminium Phosphate Gel; inactivated pertussis bacteria (Pw) 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 of 0.5 mL contains

Diphtheria Toxoid	≥ 30 IU
Tetanus Toxoid	≥ 60 IU
B. pertussis (Whole cell)	≥ 4 IU
rDNA Hepatitis B Surface Antigen	0.01 mg
Purified capsular polysaccharide of Hib (Haemophilus influenzae type b) covalently bound to 20-40 meg of Tetanus Toxoid [PRP-T]	0.01 mg
Thiomersal I.P.	≤ 0.05 mg
Aluminium Phosphate Gel equivalent to Al ⁺⁺⁺	0.625 mg
Sodium Chloride I.P.	4.5 mg
Water for Injection I.P.	q.s. to 0.5 mL

Therapeutic Indications

Shan 5[®] 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 (0.5 mL) 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, Hib and DTPw vaccines and also include the administration of HBIG at birth.

Method of Administration

Shan 5[®] 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

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 Diphtheria, Tetanus, Pertussis, HB or Hib vaccines.

As with other vaccines, the administration of Shan 5[®] should be postponed in subjects suffering from acute severe febrile illness.

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. In these circumstances the vaccination course should be continued with DT, Hib 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 Shan 5[®], 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-hyporesponsive 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 presence of high fever, 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 Shan 5[®] vaccination does not constitute contraindications.

HIV infection is not considered as a contraindication for Diphtheria, Tetanus, Pertussis, Hib 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 at least 30 minutes after vaccination.

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.

Shan 5[®] should under no circumstances be administered intravenously.

Pregnancy and lactation

As Shan 5[®] is not intended for use in adults, information on the safety of the vaccine when used during pregnancy or lactation is not available.

Clinical Experience¹

In a phase III study conducted at ten centers across India, 365 infants were vaccinated in a three-dose EPI schedule with either Shan 5[®] or the competitor vaccines. The results of this study revealed no significant difference in the seroconversion rates between Shan 5[®] and the competitor vaccines for all the five components. A total of 98.32% of the infants in Shan 5[®] 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 Shan 5[®] 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 Shan 5[®] 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 Shan 5[®] and the two competitor vaccines were comparable 4-6 weeks after the last dose of vaccines. The most commonly reported adverse events 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. Shan 5[®] was found to be safe and efficacious in infants when administered in a three-dose EPI schedule.

Presentation

0.5 mL single dose vial and prefilled syringe.

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 Shan 5[®]

Shan 5[®] is presented as suspension. Upon storage, a white deposit may be observed. The vaccine vial should be shaken adequately in order to obtain a homogeneous turbid white suspension. The vial should be visually inspected for any foreign particulate matter. Physical aspects like cap and the seal should be inspected for integrity of container closure system. In the event of either of the above being observed, discard the vaccine.

® Registered trademark

Developed, Manufactured and Marketed by

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