For the use of Registered Medical Practitioner or Hospital or Laboratory only

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Hepatitis B Vaccine (rDNA) I.P.

Shanvac®- B

QUALITATIVE AND QUANTITATIVE COMPOSITION

Shanvac®- B (Hepatitis B) vaccine is a sterile suspension containing purified major surface antigen of Hepatitis B virus manufactured by recombinant DNA technology. The antigen is produced by culture of genetically engineered cells of ***Pichia pastoris,*** methylotropic yeast, which carry the gene that codes for the major surface antigen of the Hepatitis B virus (HBV). The surface antigen expressed in ***Pichia pastoris*** cells is purified by several physiochemical steps and formulated as a suspension of the antigen adsorbed on Aluminium Hydroxide Gel. The vaccine does not contain any material of human or animal origin.

Composition

	Paediatric Dose of 0.5 mL contains	Adult Dose of 1.0 mL contains
Purified Hepatitis B Surface Antigen	0.01 mg	0.02 mg
Thiomersal I.P.	0.025 mg	0.05 mg
Aluminium Hydroxide Gel I.P. equivalent to Al^{+++}	0.25 mg	0.50 mg

THERAPEUTIC INDICATIONS

Hepatitis B vaccine is indicated for immunization against infection caused by Hepatitis B virus.

Routine vaccination

- All infants, children, and adolescents.[1]

High-risk populations

- Health care personnel in direct contact with patients (Physicians, Surgeons, Dentists, Nurses, first aid, ambulance and cleaning personnel etc.)
- Students in medical, dental and nursing schools in contact with patients.
- People who work with blood or blood products.
- A Thalassaemic/ Haemophilic/ other patient who receives blood transfusion.
- Haemodialysis and organ transplant recipients.[2]
- Military personnel on active duty.
- Prisoners, prison guards and other prison employees.
- Persons living in institutions, community homes, and the staff of these institutions.
- Household contacts and sexual partners of infected persons.[1]
- Newborn children of infected mothers.
- Persons at increased risk of disease due to their sexual practices such as promiscuous persons, male homosexuals, prostitutes, and venereal disease patients.[1]
- Injectable drug abusers.[1]
- Travelers going to and coming from high-risk countries or regions.[1]

DOSAGE AND ADMINISTRATION

- For neonates and children the recommended dosage of **Shanvac®-B** is 0.01 mg of antigen protein in 0.5 mL suspension.
- For adolescent below the age of 19 years, **Shanvac®-B** can be used at a dose of 0.01 mg of antigen protein in 0.5 mL suspension.
- For adult over the age of 19 years, the recommended dosage of **Shanvac®-B** is 0.02 mg of antigen protein in 1 mL suspension.
- **Shanvac®-B** should be administered intramuscularly.

IT SHOULD NOT BE GIVEN INTRAVENOUSLY.

SITE OF ADMINISTRATION

In neonates and infants, **Shanvac®- B** should be given in the anterolateral thigh. In adults the injection should be given in the deltoid region. The vaccine may be administered subcutaneously in patients with severe bleeding tendencies (e.g.hemophiliacs).

Shanvac®-B should not be given in the gluteal region, as the immune response may be lower.

Immunization Regimen

Protective antibody titre level is 10 mIU/mL. Primary immunization consists of three intramuscular doses of Hepatitis B vaccine following either Schedule A or Schedule B. Schedule A is recommended for those who come under high-risk category. Schedule B is recommended for routine immunization.

Schedule A

1stDose	At an elected date
2ndDose	1 month after the 1stDose
3rdDose	2 months after the 1stDose
A booster dose is recommended 12 months after the 1stDose	
A second booster dose may be required after 8 years if the titre falls below 10 mIU/mL.	

Schedule B

1stDose	At an elected date
2ndDose	1 month after the 1stDose
3rdDose	6 months after the 1stDose
A booster dose may be required after 8 -10 years if the titre falls below 10 mIU/mL.	

Immunization in special situations

- **Neonates Born to HBV Carrier Mothers**
  First dose of Hepatitis B vaccine can be administered simultaneously with Hepatitis B immunoglobulin, which must be given at a separate injection site. The immunization should start immediately after birth and preferably using 0, 1 and 2 months schedule.

- **Known/Presumed Exposure to HBV**
  First dose of Hepatitis B vaccine can be administered simultaneously with Hepatitis B immunoglobulin which however must be given at a separate injection site.

- **Chronic Haemodialysis Patients**[2]
  The recommended dosage of Hepatitis B vaccine is 0.04 mg (2 mL) using a 0, 1, 2, 6 months vaccination schedule. Anti-HBs surveillance every 3 to 6 months is warranted so as to maintain the accepted protective levels of 10 mIU/mL.

CONTRA-INDICATIONS

Shanvac®-B should not be administered to

- Subjects who are hypersensitive to any component of the vaccine or subjects who have shown signs of hypersensitivity after previous **Shanvac®B** vaccination.
- Subjects with severe febrile infections.

PRECAUTIONS

- As with any injectable vaccine, epinephrine should be available for use in case of anapylaxis or anaphylactic reaction.
- In presence of minor infection **Shanvac®- B** to be used only when clearly needed, and the possible advantage outweighs the possible risks.

WARNING

- Immune response is generally weaker for the people over 40 years of age, obese individuals, subjects with immuno-deficiency or those receiving immuno-suppressive therapy. Thus adequate anti-HBs antibody titres may not be obtained after primary immunisation course. In such subjects/patients additional doses of vaccine may be required.
- The vaccine dose not prevent infection by Hepatitis A, Hepatitis C, Hepatitis D, Hepatitis E or other pathogens known to infect the liver.
- **Pregnancy and Lactation**
  Pregnancy: Adequate human and animal data on use during pregnancy is not available. Hepatitis B vaccine should be used during pregnancy only when clearly needed, and the possible advantage outweighs the possible risks to the foetus.
  Lactation: Adequate human and animal data on use during lactation is not available. Caution should be exercised when Hepatitis B vaccine is administered to lactating women.
- If the individual is already a carrier of Hepatitis B virus with or without disease he may not respond to vaccine. However the vaccine has not been shown to have any deleterious effects.

INTERACTIONS WITH OTHER VACCINES

- Hepatitis B vaccine can be co-administered with DPT, DT and/or OPV.
- Hepatitis B vaccine can be co-administered together with measles mumps-rubella vaccines, Haemophilus influenzae b vaccine, Hepatitis A vaccine, BCG and yellow fever vaccine.

Note: Different injectables should be administered at different sites using separate needles and syringes.

Interchangeability with Other Hepatitis B Vaccines

Shanvac®- B can be used, for primary vaccination as well as for booster doses interchangeably with plasma derived or other rDNA based Hepatitis B vaccines.

ADVERSE REACTIONS

Common

Injection site: Mild soreness, indurations, erythema

Rare

Systemic: Fatigue, low-grade fever and malaise
Skin and appendages: Rash, pruritus, urticaria
Musculoskeletal system: Arthralgia, myalgia
Digestive system: Nausea, vomiting, diarrhoea and abdominal pain
Hepatobiliary system: Abnormal liver function tests
Nervous system: Dizziness and paresthesia

Extremely rare

Systemic: Anaphylaxis, serum sickness, angioedema and erythema multiforme
Musculoskeletal system: Arthritis
CVS: Syncope, Hypotension
Nervous System: Neuropathy, neuritis (including Guillain-Barre syndrome, optic neuritis), encephalitis and meningitis
Respiratory system: Bronchoconstriction-like symptoms
Lymphoid system: Lymphadenopathy

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Shanvac®-B generates specific protective immune response against HBsAg. For protection against HBV infection the anti-HBsAg titre (anti Hbs antibodies) should be above 10 mIU/mL.

Immunogenicity and Safety of Shanvac®-B

I. Infants & Children

In six controlled studies conducted in infants and children using 0,1,2 months and 0,1,6 months vaccination schedule. **Shanvac®- B** has shown 100% seroprotection after 3rd dose with GMT ranging from 643 mIU/mL to 2643 mIU/mL and 17611 mIU/mL to 19183 mIU/mL respectively.[3,4,5,6]

II. Healthy Adults

In eight controlled studies **Shanvac®- B** has shown seroconversion in 96.4% subjects with a GMT ranging from 2.2 mIU/mL to 10446 mIU/mL after 3rd dose vaccination.[7,8,9]

III. Studies In High Risk Groups

Study in patients with chronic renal failure **Shanvac®- B** showed seroprotection in 80% of patients with a GMT of 218 mIU/mL after 3 rd dose of 0,1,2 schedule.[2]

Shanvac®-B showed 100% seroprotection in a study of haemophiliac patients, with GMT of 2767 mIU/mL after third dose of 0,1,6 schedule.[4]

IV. Long Term Efficacy

Even four years after vaccination with **Shanvac®- B** 100% of subjects were seroprotected. The GMT after four years was 306 mIU/mL and 832 mIU/mL after last dose 0,1, 6 and 0,1,2,12 schedule respectively.[4]

PHARMACEUTICAL DETAILS

Preparation for Administration

- **Shanvac®-B** is presented as a ready to use suspension.
- The vaccine should be shaken well to obtain a homogenous turbid white suspension.
- The vaccine should be inspected visually for particulate material or discolouration prior to administration.
- Sterile needle and syringe should be used for withdrawal of vaccine.
- Aseptic techniques should be followed .
- Physical aspects like cap and the seal should be inspected for integrity of container closure system.

Shelf Life

36 months from the date of manufacture.

Special Precautions for Storage

Protect from light. **DO NOT FREEZE.** Discard vial if contents are frozen. **Stored and transported between +2°C to +8°C.**

Presentation

0.5 mL, 1.0 mL, 2.0 mL (for Immuno-Compromised Patient), 2.5 mL, 3.0 mL, 5.0 mL and 10 mL vials.

LEGAL CATEGORY
Schedule H

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REFERENCES

1.ACIP. *MMWR* 1999/48(02);33-34.
2.*Indian J Nephrol* 1998;8:141.
3.*Indian Pediatrics* 2000;37:75-80.
4.*Indian Pediatrics* 1999;36:581-583.
5.*Indian Journal of Gastroenterology* 1999;18:S24-S25.
6. *DATA ON FILE:* Shantha Biotechnics Limited
7. *Vaccine* 1999;17:1125-1129
8. *JAPI* 1998;46:620-622.
9.*Indian Journal of Gastroenterology* 2000;19:71-73

Developed, Manufactured & Marketed by
Shantha Biotechnics Limited
Survey No. 274, Athvelli Village,
Medchal Mandal-501 401,
Ranga Reddy District, Andhra Pradesh, INDIA.
Tel: +91 -40-23234104, 23234105,
23234135, 23234136.
Fax: +91-23234103, 23234133
Email:info@shanthabiotech.co.in
Web :www.shanthabiotech.com

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