Sci-B-Vac™

Hepatitis B Vaccine (rDNA)

Description

Sci-B-Vac [Hepatitis B Vaccine (rDNA)] is a third generation vaccine produced by culture in Chinese hamster ovary cells. It consists of 22 nm particles isolated and purified from culture medium. The particles contain all three epitopes of hepatitis B surface antigen (HBsAg), namely S, pre-S_1 and pre-S_2, in their glycosylated and non-glycosylated forms, embedded in a phospholipid matrix, thus resembling the authentic plasma derived HBsAg. The antigen is formulated by adsorption onto aluminum hydroxide. The final preparation is virtually free of DNA and contains less than 3% protein contaminants. It does not contain any known animal viruses, bacteria or *Mycoplasma*.

Composition:

Active ingredient:

Sci-B-Vac 10µg/ml contains hepatitis B surface antigen 10µg/ml

Sci-B-Vac 5µg/0.5ml contains hepatitis B surface antigen 5µg/0.5ml

Sci-B-Vac 2.5µg/0.5ml contains hepatitis B surface antigen 2.5µg/0.5ml

Other ingredients:

$Al(OH)_3$ (2% solution) 0.5ml/1ml equivalent to dry weight of 1.5mg $Al(OH)_3$ per mL,

NaCl, KCl, $Na_2HPO_4 \times 12H_2O$, KH_2PO_4, WFI.

Each batch of the vaccine is rigorously tested for purity, safety, sterility and potency.

In each formulation, the HBsAg is adsorbed onto approximately 0.5 mg of aluminum per ml of vaccine.

Indications and Usage

Sci-B-Vac is indicated for active immunization against hepatitis B virus (HBV) infection.

Immunization against hepatitis B is expected, in the long term, to reduce not only the incidence of the disease, but also its chronic complications such as massive hepatic necrosis, cirrhosis of the liver and hepatocellular carcinoma.

Vaccination with Sci-B-Vac is recommended for all ages in those subjects who are or will be at increased risk of infection with HBV. In areas of high prevalence of infection, the majority of the population is at high risk, especially neonates and children. In high risk areas, infection occurs primarily through mother to child and horizontal transmission. Therefore, vaccination should be targeted to prevent such transmission. In areas of intermediate and low prevalence, vaccination is recommended for neonates, infants and adolescents, as well as subjects who are or will be at increased risk of infection, such as:

- Health care personnel
- Frequent recipients of blood products
- Infants born to HBsAg-positive mothers
- Personnel and residents of public health institutions
- Persons at increased risk of the disease due to their sexual practices
- Travelers to areas with high endemicity of HBV
- Persons originating from areas of high endemicity
- Users of illicit injectable drugs
- Military personnel, police personnel and anybody who through their work or personal lifestyle may be exposed to HBV
- Family members and others in intimate contact with persistent HBsAg-positive individuals.

Persons who develop anti-HBs antibodies following active infection with the hepatitis B vaccine are protected against the disease if they are re-exposed to the virus.

Clinical trials have shown that Sci-B-Vac induced protective levels of antibody in up to 100% of healthy adults who received the recommended three-dose regimen of 10 µg/dose.

Sci-B-Vac is highly immunogenic in children. The specific antibody titers tend to be an order of magnitude higher in children than in adults when the recommended doses are administered. Children tend to achieve seroprotection more frequently than adults.

Contraindications

Sci-B-Vac should not be administered to subjects with known hypersensitivity to any components of the vaccine or to subjects who developed symptoms suggestive of hypersensitivity after the injection of Sci-B-Vac.

As with other vaccines, the administration of Sci-B-Vac should be postponed in subjects suffering from acute severe illness. The presence of a minor infection, however, is not a contraindication for immunization.

Warnings

Due to the long incubation period for hepatitis B, it is possible for unrecognized infection to be present at the time of vaccination. Vaccination may not prevent hepatitis B in such individuals. The vaccine will not prevent infection caused by other agents such as hepatitis A, hepatitis C and hepatitis E or other pathogens known to infect the liver.

Precautions

General: As with any vaccine, epinephrine should be available for immediate use should an anaphylactic reaction occur.

Caution and appropriate care should be exercised in administering the vaccine to individuals with severe compromised cardiopulmonary status or to others in whom a febrile or systemic reaction could pose a significant risk.

Sci-B-Vac should under no circumstances be administered intravenously.

Pregnancy and Nursing Mothers: Animal reproduction studies have not been conducted with the vaccine. It is

also not known whether the vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The vaccine should be given to a pregnant woman only if clearly needed. It is not known whether the vaccine is excreted in human milk. Since many drugs are excreted in human milk, caution should be exercised when the vaccine is administered to a nursing woman.

Pediatric Use: Sci-B-Vac has been shown to be well tolerated and highly immunogenic in infants and children of all ages. Newborns also respond well; maternally transferred antibodies do not interfere with the active immune response to the vaccine.

Adverse Reactions

Sci-B-Vac is generally well tolerated. No serious adverse reactions attributable to the vaccine have been reported during the course of clinical trials. As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials.

In a series of studies, 2313 doses of Sci-B-Vac were administered to 771 healthy adults who were monitored for 5 days after each dose. The following adverse reactions were reported:

Incidence Equal to or Greater Than 1% of Injections:
Local Reaction (Injection Site): Injection site reactions consist of soreness and include pain, tenderness, pruritus, erythema, ecchymosis, swelling, warmth and nodule formation. These reactions were mild and resolved within two days after vaccination.

Additional complaints included fatigue/weakness, headache, fever (37.8°C), malaise, nausea, diarrhea pharyngitis and upper respiratory infection.

Incidence Less Than 1% of Injections:
Sweating, aching, sensation of warmth, light-headedness, chills, flushing, vomiting, abdominal pains/cramps, dyspepsia, diminished appetite, rhinitis, influenza, cough, vertigo/dizziness, paresthesia, pruritus, rash (non-specified), angioedema, urticaria, arthralgia including monarticular, myalgia, back pain, neck pain, shoulder pain, neck stiffness, lymphadenopathy, insomnia/disturbed sleep, earache, dysuria and hypotension.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

https://sideeffects.health.gov.il/

Dosage and Administration

Sci-B-Vac is a sterile suspension for intramuscular injection.

Adult Formulation, 10 µg/ml: each 1 ml dose contains 10 µg hepatitis B surface antigen; recommended for children above the age of 10 years and adults.

Pediatric Formulation (option 1) 2.5 µg/0.5 ml: each 0.5 ml dose contains 2.5 µg hepatitis B surface antigen; recommended for neonates, infants and young children.

Pediatric Formulation (option 2) 5 µg/0.5 ml: each 0.5 ml dose contains 5 µg hepatitis B surface antigen; recommended for neonates, infants and young children in highly endemic areas.

In each formulation, the hepatitis B surface antigen is adsorbed onto approximately 0.5 mg of aluminum per ml of vaccine.

Method of Administration: Sci-B-Vac should be injected intramuscularly into the deltoid muscle in adults and children or in the anterolateral thigh in neonates, infants and young children. The vaccine may be administered subcutaneously to persons who are at high risk of hemorrhage due to thrombocytopenia or bleeding disorders. **Do not inject into the gluteal muscle.**

Vaccination Schedule: The vaccination regimen for all subjects consists of three (3) doses of vaccine given according to the following schedule: first dose at elected date; second dose 1 month after the first dose; third dose 6 months after the first dose.

Booster Dose: The duration of the protective effect of Sci-B-Vac against HBV is unknown at present. A booster dose may be considered when the anti-HBs titer falls below 10 mIU/ml.

As with all parenteral drug products, the vaccine should be inspected visually for any particulate matter and/or discoloration prior to administration.

Before use of Sci-B-Vac, the vaccine should be shaken well to obtain a slightly opaque, white suspension. Discard if the contents of the vial appear otherwise. As with other vaccines, a dose of vaccine should be withdrawn under aseptic conditions and precautions taken to avoid contamination of the contents.

Recommended Storage Conditions:

The vaccine should be stored in the dark at +2°C to +8°C. **Do Not Freeze.**

Manufactured and Distributed by:

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