

Package Insert of EnivacHB (UNICEF)

Size: 217x100 mm



Hepatitis B Vaccine (rDNA) IP (Genetically Engineered)

EnivacHB

DESCRIPTION

Hepatitis B Vaccine (rDNA) IP (EnivacHB) is a sterile, opaque, uniform suspension of Hepatitis B surface antigen adsorbed on Aluminium Hydroxide to which thiomersal is added as a preservative. Surface antigen of the Hepatitis B virus (HBV) is obtained from cultures of a transformed yeast by the insertion in its genome of the gene coding for the surface antigen (HBsAg) using recombinant DNA procedures. The production process of EnivacHB vaccine complies with WHO recommendations.

The final product has the appearance of a white or almost white suspension which may sediment at the bottom of the container on storage separating into two phases: a clear supernatant, essentially protein-free containing preservative substance and Aluminium Hydroxide gel with adsorbed antigen. When shaken, a white or almost white suspension is formed, lasting for some minutes, which is the form in which the product should be administered. The upper limit of relative potency (in vivo and in vitro) is equal to or more than 1.0.

COMPOSITION

	<u>Paediatric Dose</u>
Each paediatric dose contains :	0.5 ml
Recombinant Purified HBsAg	10 mcg
Aluminium (Al ³⁺) (As Aluminium Hydroxide gel IP)	0.25 mg
Thiomersal IP	0.025 mg
Water for Injection IP	qs

ADMINISTRATION

The liquid vaccine vial should be shaken before use to homogenize the suspension. It should be injected intramuscularly into the anterolateral aspect of the thigh in infants, or into the deltoid muscles of older children or adults. An injection into a child's buttocks may cause injury to the sciatic nerve and is not recommended. A sterile syringe and sterile needle must be used for each injection.

IMMUNIZATION SCHEDULE

There are multiple options for administration of the hepatitis B vaccine and guidelines of the national immunization programme should be consulted. The choice of schedule should depend on national policy which is based on the local epidemiological situation and programmatic considerations. The minimum recommended interval between the doses is four weeks. Longer dose intervals may increase the final anti-HBs titres but not the seroconversion rates. More than 3 doses of the vaccine are not required, regardless of duration (> 4 weeks) of the interval between them.

Recommended schedules for vaccination can be divided into those that include a birth-dose and those that do not. Schedules with a birth-dose call for the first vaccination at birth (within 24 hours), followed by a second and third dose at the time of the first and third diphtheria-tetanus-pertussis (DTP) vaccination, respectively. Alternatively, a four-dose schedule may be used where the dose at birth is followed by three additional doses; these doses may be given either as monovalent vaccine or as a combination (e.g. with DTP and/or Hib) following the schedules commonly used for those vaccines. These schedules will prevent most perinatally acquired infection.

Hepatitis B vaccine can be given safely and effectively at the same time as BCG, DTP, measles, polio (OPV or IPV), *Haemophilus influenzae* type b, or yellow fever vaccines or vitamin A supplementation. If hepatitis B vaccine is given at the same time as other vaccines, it should be administered at a separate site. It should not be mixed in the vial or syringe with any other vaccine unless it is licensed for use as a combined product (e.g. DTP-Hep B/DTPHepB-Hib).

SIDE EFFECTS

The vaccine is very well tolerated. Reports of severe anaphylactic reactions are very rare. Available data do not indicate a causal association between hepatitis B vaccine and Guillain-Barre syndrome, or demyelinating disorders including multiple sclerosis, nor is there any epidemiological data to support a causal association between hepatitis B vaccination and chronic fatigue syndrome, arthritis, autoimmune disorders, asthma, sudden infant death syndrome, or diabetes.

CONTRAINDICATIONS

Known hypersensitivity to any component of the vaccine, or a severe reaction to a previous dose. The vaccine will not harm individuals currently or previously infected with the hepatitis B virus.

Immune deficiency

Individuals infected with human immuno-deficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with hepatitis B vaccine according to standard schedules.

STORAGE

Hepatitis B vaccine must be stored and transported between 5°C ± 3°C.

IT MUST NOT BE FROZEN.

Multi-dose vials of hepatitis B vaccine from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to a maximum of 4 weeks, provided that all of the following conditions are met (as described in the WHO policy statement: *The use of opened multi dose vials in subsequent immunization sessions. WHO/V&B/00.09*):

- 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 withdraw all doses;
- The vaccine vial monitor (VVM) has not reached the discard point (see figure).

PRESENTATION

Single paediatric dose vial containing 0.5 ml vaccine.





Single Adult dose vial containing 1.0 ml vaccine.

Ten paediatric doses vial containing 5.0 ml vaccine.

Ten Adult doses vial containing 10.0 ml vaccine.

Figure of the Vaccine Vial Monitor (VVM)

The vaccine vial monitor ...

-  ✓ Inner square is lighter than outer circle. **If the expiry date has not been passed, USE the vaccine.**
-  ✓ At a later time, inner square still lighter than outer circle. **If the expiry date has not been passed, USE the vaccine.**
-  ✗ **Discard point :** Inner square matches colour of outer circle. **DO NOT use the vaccine.**
-  ✗ **Beyond the discard point :** Inner square darker than outer circle. **DO NOT use the vaccine.**

Vaccine Vial Monitors (VVMs) are part of the label on hepatitis B vaccine vial. The colour dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The interpretation of the VVM is simple. "Focus on the central square". Its colour will change progressively. As long as the colour of this square is lighter than the colour of the circle, the vaccine can be used. As soon as the colour of the central square is the same colour as the circle or of a darker colour than the circle, the vial should be discarded.

Manufactured by:

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