SUMMARY OF PRODUCT CHARACTERISTICS

(SPC)

Product Name	**: Recombinant Hepatitis B Vaccine**
Pharmaceutical Form	**: Suspension for injection**
Strength	**: Single dose of 0.5 mL or 1 mL**
Presentation	**: Single dose of 0.5 mL or 1 mL in prefill injection device** **Box of 10 pouches @ 0.5 mL** **Box of 100 pouches @ 0.5 mL** **Box of 10 pouches @ 1.0 mL**

PT. Bio Farma (Persero)
Bandung - Indonesia

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Product Name:

Recombinant Hepatitis B Vaccine

1.2 Strength:

Single dose of 0.5 mL and 1 mL

1.3 Pharmaceutical dosage form:

Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The vaccine is a liquid containing highly purified, non-infectious particles of hepatitis B surface antigen (HBsAg) produced by DNA recombinant technology in yeast cells. The vaccine is adsorbed onto 0.5 mg/mL of Aluminum hydroxide. Thimerosal 0.01% is used as preservative. The potency of the vaccine is at least 0.56 by in vitro test (in-house reference potency).

Composition :	**Pediatric dose (< 10th years)**	**Adult dose (≥ 10th years)**
Volume	0.5 mL	1.0 mL
Hepatitis B surface antigen	10 µg	20 µg
Aluminum Hydroxide	0.025 mg	0.5 mg
Thimerosal	0.01% w/v	0.01% w/v

3. PHARMACEUTICAL FORM

White suspension, packaged in prefill injection device.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

Active immunization against hepatitis B.

4.2 Posology and method of administration:

The vaccine used be shaken before use. 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 on into a child's buttocks may cause injury to the sciatic nerve and is not recommended. The pediatric dose is 0.5 mL and adult dose is 1.0 mL. A sterile syringe and sterile needle should be used for each injection.

There are multiple options for administration of hepatitis B vaccine and guidelines of 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 interval may increase the final anti-HBs titers but not 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 divide into those that include a birth-dose and those that do not. Schedules with a birth dose for the first vaccination at birth (within 24 hours), followed by a second and third dose at the time at 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 dose; these doses may be given either as monovalent vaccine or as a combination (e.g with DTP and/or Hib) following schedules commonly used for those vaccine. 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), *Haemophillus influenza* type b or Yellow fever vaccines. 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 manufactured as a combined product (e.g. DTP-HB / DTP-HB-Hib).

4.3 Contraindications:

Hypersensitive to any component of the vaccine. As for any vaccine, Recombinant Hepatitis B vaccine should not be administered to subjects with severe febrile infections. However the presence of a trivial infection does not contraindicate with vaccination.

Immune deficiency

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

4.4 Special warnings and precautions for use:

- The vaccine should be shaken before use.
- The vaccine should be injected intramuscularly
- Before use, the information on Vaccine Vial Monitor (VVM) must be followed.
- The effect of antigen on foetal development is unknown and therefore general vaccination of pregnant women cannot be recommended. However, vaccination of a pregnant women may be considered in order to prevent Hepatitis B in high- risk situation. As with all biologicals, epinephrine should always be readily available for

immediate use in case of anaphylactic reactions. Because of the long incubation period of hepatitis B, it is possible for unrecognized infection to be present at the time of vaccination.

- Recombinant Hepatitis B vaccine should not be administered in the gluteal region or intradermally since these routes of administration may not result in an optimum immune response.
- Recombinant Hepatitis B vaccine should not be administered intravenously. In dialysis patients and such subjects who have an impairment of the immune system adequate antibody concentration may not be obtained after the usual primary vaccination course and such patients may therefore require repeated administration of the vaccine.
- 'RISK OF SENSITIZATION IN RELATION TO THIOMERSAL AND OTHER PRESERVATIVES'.

4.5 Interaction with other medicinal products and other forms of interaction:

No interaction studies have been performed.

4.6 Pregnancy and lactation:

No related study has been performed. There are no adequate data from the use of Bio Recombinant Hepatitis B Vaccine in pregnant women and during lactation. There is no evidence of risk to the fetus or infants. However, Bio Recombinant Hepatitis B Vaccine should only be used during pregnancy and lactation when there is a clear risk of hepatitis B infection and when the benefit outweighs the risk.

4.7 Effects on ability to drive and use machines:

No studies on the effects on the ability to drive and use machines have been performed. There is no evidence that Recombinant Hepatitis B Vaccine affects the ability to drive and use machines.

4.8 Undesirable effects:

The vaccine is very well tolerated. Some temporary swelling, tenderness and redness at the site of the injection occurs in some individuals (about 12%). Other minor reaction such as malaise or fever occur in less than 2% of individuals. More serious reaction are rare; a causal relationship between more serious reactions and the vaccine has not been established.

4.9 Overdose:

No case of overdose in humans has been reported. No serious adverse reactions are expected to result from overdose with Bio Recombinant Hepatitis B Vaccine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics Properties:

- Pharmacotherapeutic group : Vaccines
- ATC code : J07BC01
- Mechanism of action (if known) : Stimulates the body to produce antibody against Hepatitis virus.
- Pharmacodynamics effects : No study has been performed.
- Clinical efficacy and safety : Refer to sections 2.5, 2.7 and module 5 of the CTD.

5.2 Pharmacokinetic Properties:

Not applicable

5.3 Preclinical safety data:

No related study has been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients:

Aluminum hydrixide
Sodium chloride
Thimerosal

6.2 Incompatibilities:

No related study has been performed.

6.3 Shelf life:

The shelf life of Hepatitis B Vaccine is 26 months, stored at +2°C and +8°C. The expiry date is shown on the label.

6.4 Special precautions for storage:

Hepatitis B Vaccine should be stored and transported between +2°C and +8°C, it must not be frozen.

6.5 Nature and contents of container:

Hepatitis B Vaccine comes in single pediatric dose 0.5 mL and single 1 mL prefill injection device.
Box of 10 pouches@ 0.5 mL
Box of 100 pouches@ 0.5 mL
Box of 10 pouches@ 1.0 mL

6.6 Instructions for use, handling and disposal:

Shake well before use.

7. MARKETING AUTHORIZATION HOLDER

PT. Bio Farma (Persero)
Jalan Pasteur No. 28
Bandung 40161
Indonesia
Telephone : +62 22 2033755
Telefax : +62 22 2041306
E-mail : mail@biofarma.co.id
Website : www.biofarma.co.id

8. MARKETING AUTHORIZATION NUMBERS

GKL9802905543A1

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorization:

9 February 1999

Date of renewal of the authorization:

18 May 2017 for Hepatitis B vaccine 1.0 mL

28 April 2016 for Hepatitis B vaccine 0.5 mL

10. DATE OF REVISION OF THE TEXT

August 2020