SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Revac-B*mcf*®

Hepatitis-B Vaccine (r-DNA)

1. NAME OF THE MEDICINAL PRODUCT

Name of the product: Hepatitis-B Vaccine (r-DNA)
Strength:
a) Each pediatric dose of 0.5 mL contains
Hepatitis B surface Antigen (HBsAg)…….. ≥10 µg
b) Composition: Each adult dose of 1.0 mL contains
Hepatitis B surface Antigen (HBsAg)……... ≥20 µg
Pharmaceutical Form: Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition: Each pediatric dose of 0.5 mL contains
Hepatitis B surface Antigen (HBsAg)…….. ≥10 µg
Aluminum Hydroxide Gel equivalent to Aluminum (Al^{+++})….. 0.25 mg
Phosphate Buffered Saline ……..…… q.s. to 0.5 mL

b) Composition: Each adult dose of 1.0 mL contains
Hepatitis B surface Antigen (HBsAg)……... ≥20 µg
Aluminum Hydroxide Gel equivalent to Aluminum (Al^{+++})…… 0.5 mg
Phosphate Buffered Saline…….……. q.s. to 1.0 mL

3. PHARMACEUTICAL FORM

Suspension for Injection

4. CLINICAL PARTICULARS

4. 1 Therapeutic Indication

Revac-B *mcf*® is indicated for the immunization of persons against infection by hepatitisB virus and its common subtypes. It can also be administered to patients infected by hepatitis C and D viruses.

Revac-B *mcf*® offers protection against co-infection with hepatitis-B virus. **Revac-B *mcf*®** is recommended primarily for neonates, infants and young adults. It not only prevents the disease but also confers protection against hepatitis-B virus (induced carrier state), cirrhosis and hepatocellular carcinoma. In addition, **Revac-B *mcf*®** immunization is an essential requirement for the following subset of people:

- Healthcare personnel.
- Patients prone to infection due to unscreened or improperly tested blood transfusions.
- Hemophiliacs and patients on haemodialysis.
- Travellers to highly endemic areas.
- Residents in high endemic areas.

- Persons in contact with infected sexual partners.
- Drug abusers.
- Personnel and residents of community homes and hostels.
- Household contacts of persons with acute or chronic HBV infection.
- Infants born to HBV carrier mothers.
- Organ transplant receivers.
- Others: Police, Armed forces and other regimented personnel.

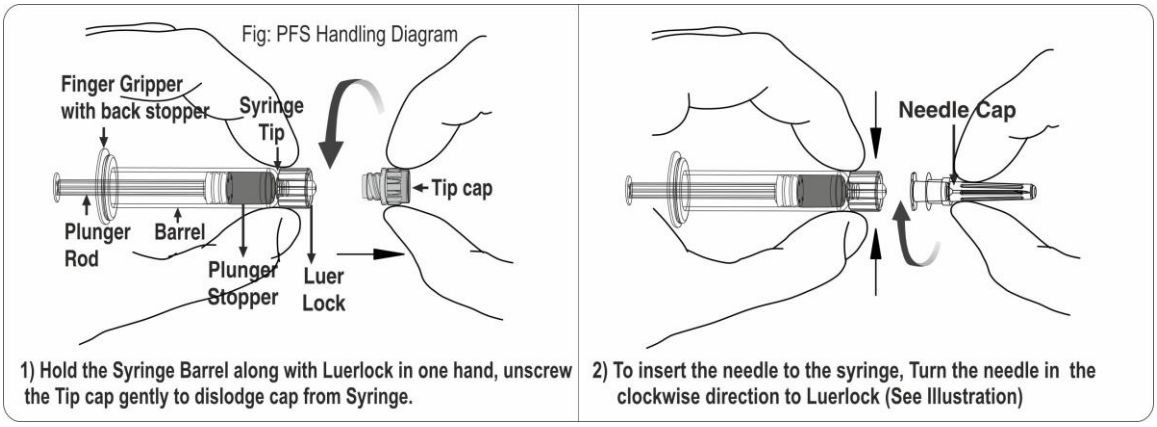
Revac-B *mcf*® is specifically advantageous for babies with neurodevelopmental disorders and possible neurosuppressant complications. It also allows normal immunization for low birth weight and preterm infants, which might otherwise be delayed.

4.2 Posology and Method of Administration

Revac-B *mcf*® should be injected intramuscularly into the deltoid region of adults and the anterolateral aspect of the thigh in neonates, infants and young children. **Revac-B *mcf*®** should NOT be injected into the gluteal muscle. This route of administration may result in lower immune response. Under no circumstance **Revac-B *mcf*®** should be given intravenously.

PFS Handling Procedure:
Prior to administration, ensure that the plunger rod is firmly attached to the rubber stopper by turning the plunger rod clockwise until slight resistance is felt. Do not over-tighten. Hold the Syringe Barrel along with the Luer-lock in one hand, unscrew the Tip cap gently to dislodge the cap from Syringe and fix the needle on the syringe by turning in clockwise direction into Luer-lock until it is securely fixed to the syringe; remove the needle cap before injecting. Do not rotate Luer-lock. A finger grip with a back stopper will prevent the Plunger rod from coming out from the syringe Barrel.

"Do not remove the back-stopper from the syringe."



Dosage and Schedule

As indicated in the composition, a dose of 20 µg in 1 mL is formulated for adults and children above 10 years of age. A dose of 10 µg in 0.5 mL is recommended for neonates, infants, and children below 10 years of age.

Immunization schedule:

A. Primary immunization schedule: An interval of 30 days is maintained between the administration of FIRST and SECOND doses, followed by a THIRD dose, 180 days after the first.	
1st dose	on selected date
2nd dose	30 days after the first dose
3rd dose	180 days after the first dose
B. Special dosage recommendations: The dose recommended to neonates, born to HBV infected mothers is as follows:	
1st dose	on selected date
2nd dose	30 days after the first dose
3rd dose	60 days after the first dose
Booster dose	1 year after the first dose

Additional passive immunization with Hepatitis-B immunoglobulin (HBIg) is recommended for immune-compromised individuals or persons exposed to HBV infection upon advice from a registered medical practitioner. Please refer to the package insert of HBIg product from the respective manufacturer for its use.

4.3 Contraindications

Revac-B *mcf*® is generally well tolerated. However, the vaccine should not be administered or re-administered to persons who are known to be hypersensitive to any of its components. Avoid immunization during severe febrile illness.

4.4 Special warning and Precautions for use

It is suggested that medical practitioners ascertain the pre-immunization hypersensitivity status of the subject. In general, biologicals are known to cause reactions occasionally. Sympathomimetic drugs such as adrenalin should be readily available in case of any anaphylactic reactions due to the vaccine.

Shake well before use to obtain a uniform, whitish translucent suspension. Prior to administration, the vaccine should be visually checked for the presence of any particulate matter or other coloration. In case of doubt, do not use the contents of the vial.

Revac-B *mcf*® can be co-administered with BCG, DPT, and OPV vaccines extensively used in the Universal Immunization Programme (UIP). During concomitant administration with other UIP vaccines, **Revac-B *mcf*®** should always be administered at a different injection site.

Revac-B *mcf*® should not be mixed with other vaccines.

NOTE: Because of the long incubation period of hepatitisB virus infection, some subjects may receive the vaccine while the infection remains unrecognized. In such cases, the vaccine may not prevent the onset of hepatitis.

Revac-B *mcf*® will not prevent hepatitis caused by other viruses, such as hepatitis A, hepatitis C, hepatitis D and other agents known to infect the liver.

An overdose of this vaccine is unlikely to occur. If a higher dose is administered to children, it is unlikely to cause any harm. However, there is no such evidence available. There is no treatment for an overdose of Hepatitis B vaccine. Contact your doctor if you miss a dose in the schedule. The next dose should be administered as soon as possible.

No withdrawal symptoms have been recorded for this product. A full course of vaccination is needed to ensure complete protection against the disease.

4.5 Interaction with other medicinal products/active immunising agents and other forms of interaction

For concomitant or co-administration, use different injection sites and separate syringes.

Revac-B *mcf*® should not be mixed with any other vaccine or medicinal product because interactions with these products have not been established.

4.6 Pregnancy and Lactation
Safety and effectiveness have not been established in pregnant women and nursing mothers.

4.7 Effect on ability to drive and use machines
No studies on the effect of **Revac-B *mcf*®** on the ability to drive and use machines have been performed.

4.8 Undesirable Effects:
Revac-B *mcf*® has proven low reactogenicity and is well tolerated. Inflammation at the injection site or a febrile reaction may be observed in some subjects. No serious adverse event was reported after vaccination in the phase IV clinical trial. Adverse events like fever and persistent crying were observed in 5.2% and 1.1%, respectively.

In rare cases of post-vaccination hypersensitivity, common symptoms that are quickly recognised by a physician are dizziness, headache, nausea, abdominal pain, rash, pruritus, urticaria, arthralgia, myalgia and other similar associated symptoms.

Strict adherence to the aforementioned precautions is advised to avoid untoward reactions.

4.9 Over Dose
No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties
Revac B *mcf*® generates specific protective immune response against HBsAg. For protection against HBV infection, the anti-HBsAg titer (Anti HBs Anti bodies) should be ≥ 10 mIU/ml.

5.2 Pharmacokinetic Properties
Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data
Not Applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients
Aluminium (Al^{+++}) as Aluminium hydroxide gel

6.2 Incompatibilities
This medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life
The expiry date of the vaccine is indicated on the label and carton of the product.

6.4 Special Precautions for Storage

Store at +2°C to +8°C. Do not freeze.

Discard if frozen. Shake well before use.
Protect from light. Keep out of reach of children.
Do not use the vaccine after the expiration date shown on the label.
Opened vial should be used within 6 hours when stored at +2°C to +8°C.

6.5 Nature and contents of the container

Revac-B *mcf* ® is available in single-dose vials and Pre-Filled Syringes
Single dose PFS (Paediatric dose): 0.5mL
Single dose vial (Paediatric dose): 0.5mL
Single dose vial (Adult dose):1.0mL

6.6 Special precautions for disposal
Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Bharat Biotech International Limited situated

Sy. No. 230, 231 & 235, Genome Valley,

Turkapally, Shamirpet Mandal,

Medchal, Malkajgiri District, Telangana State, India, Pin: 500078.

8. MARKETING AUTHORISATION NUMBER
12-30/86-DC

9. DATE OF FIRST MARKETING AUTHORISATION
14 OCT 1998

10. DATE OF REVISION
January 2023