℞ For use by a Registered Medical Practitioner or Hospital or Laboratory only

रिकॉम्बीनेन्ट हेपेटाइटिस-बी वैक्सीन आई पी

Recombinant Hepatitis B Vaccine IP

Revac-B*mcf*® रिवैक-बी एम सी एफ®

Thiomersal Free

1. NAME AND DESCRIPTION OF THE MEDICINAL PRODUCT:

Revac-B *mcf*® is a sterile suspension containing a purified, surface antigen of hepatitis-B virus. It is produced by recombinant DNA technology. The antigen is adsorbed on high affinity aluminium hydroxide gel molecules. Accordingly, the suspension appears white and translucent. The vaccine fulfills WHO requirements for recombinant Hepatitis-B Vaccine.

Recombinant Technology:

Hepatitis-B surface Antigen (HBsAg) is produced in genetically engineered yeast cells (*Pichia pastoris*). They carry a gene that codes for a major surface antigen protein of hepatitis-B virus. HBsAg is purified by complex physical, chemical and biochemical processes. The antigen assembles spontaneously into spherical particles, that have a diameter of 20-24nm. These spherical particles contain non-glycosylated polypeptides in a lipid matrix. Extensive and rigorous R&D processes have characterised and confirmed that these 20-24nm spherical particles resemble the natural HBsAg protein in their antigenic properties. Efficacy and safety of **Revac-B *mcf*®** is ensured, through stringent adherence to bio-process control and quality assurance measures. No substance of human origin is used in the manufacture of HBsAg protein.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each dose of 0.5mL contains: (Paediatric Dose)
Hepatitis B Surface Antigen..... ≥10 µg
Aluminium (Al^{+++}) as Aluminium Hydroxide Gel..... 0.25 mg
Phosphate buffered Saline..... q.s. to 0.5 mL
Each dose of 1mL contains: (Adult Dose)
Hepatitis B surface Antigen..... ≥20 µg
Aluminium (Al^{+++}) as Aluminium Hydroxide Gel..... 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 immunization of persons against infection by hepatitis-B virus and it's common sub-types. It can also be administered to patients infected by hepatitis C and D viruses. This 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 such other regimented personnel.

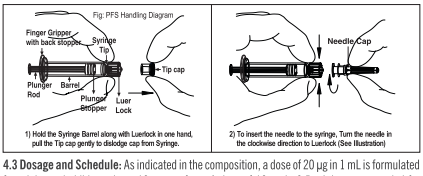
Revac-B *mcf*® is specifically advantageous for babies with neuro-developmental disorders and possible neuro-suppressant complications. It also allows normal immunization for low birth weight and preterm infants, which otherwise might be delayed.

4.2 Posology and Method of Administration:

Revac-B *mcf*® should be injected intramuscularly into the deltoid region of adults and antero-lateral 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. Remove rubber tip-cap from the syringe and fix the needle on syringe by turning in clock wise direction into luer lock until it is securely fixed to the syringe, remove the needle cap before injecting. Do not rotate luer lock. Finger grip with back stopper will prevent Plunger rod coming out from the syringe Barrel. "Do not remove the back-stopper from the syringe."



4.3 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 of 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.

4.4 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 the components of the vaccine. Avoid immunization during severe febrile illness.

4.5 Special warning / Precautions:

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 kept readily available in case of any anaphylactic reactions due to the vaccine.

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

Revac-B *mcf*® can be co-administered with BCG, DPT, and OPV vaccines which are 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 hepatitis-B 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 over dose 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.

Withdrawal symptoms have not been recorded for this product. In order to ensure complete protection against the disease, full course of vaccination needs to be completed.

4.6 Interaction with other medicinal products/ 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 the interactions with other vaccines or medical products have not been established.

4.7 Pregnancy and Lactation

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

4.8 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.

4.9 Undesirable Effects:

Revac-B *mcf*® has proven low reactogenicity and is well tolerated. Inflammation at the site of injection or a febrile reaction may be observed in some subjects. In a phase IV clinical trial, no serious adverse event was reported after vaccination. 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 in order to avoid untoward reactions.

4.10 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.

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.

7. PRESENTATION

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

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Manufactured & Marketed by :

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