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+®

DESCRIPTION:

Revac-B+® is a sterile suspension containing purified, non-infectious major surface antigen of the hepatitis-B virus and is manufactured by recombinant DNA technology. The antigen is adsorbed onto high affinity aluminium hydroxide gel molecules and hence the suspension appears almost white and translucent.

The Vaccine fulfills WHO Requirements for Hepatitis-B Vaccine made by recombinant DNA techniques.

RECOMBINANT TECHNOLOGY:

The Hepatitis-B surface Antigen (HBsAg) is produced in genetically engineered yeast cells of *Pichia pastoris* which carry the gene that codes for the major surface antigen protein of the hepatitis-B virus. HBsAg expressed in yeast cells is purified by complex physical, chemical and biochemical processes. The resultant highly purified surface antigen assembles spontaneously into spherical particles of an average diameter of 20-24nm containing non-glycosylated polypeptides in a lipid matrix. An extensive and rigorous R&D processes characterised and confirmed that these 20-24nm spherical particles resemble the natural HBsAg protein in their antigenic properties. The efficacy and safety of the formulated **Revac-B+®** is ensured through stringent adherence to the highest standards of bio-process control and consistent Quality Assurance measures. **No substance of Human origin is used in the manufacture of HBsAg protein.**

Composition	Paediatric Dose	Adult Dose
Volume	0.5 mL	1.0 mL
Hepatitis B Surface Antigen	≥10 µg	≥ 20 µg
Aluminium (Al^{+++}) as Aluminium Hydroxide Gel	0.25 mg	0.5 mg
Thiomersal IP	0.025 mg	0.05 mg
Phosphate buffer saline	q.s to 0.5 mL	1.0 mL

INDICATIONS FOR IMMUNIZATION:

Revac-B+® is indicated for immunization of persons against infection by hepatitis-B virus and its common sub-types. It can also be given to hepatitis C and D virus infected patients to protect them against co-infection with hepatitis-B virus. **Revac-B+®** is recommended primarily for neonates, infants and young adults not only for the prevention of the disease but also to protect them from probable hepatitis-B virus - induced carrier state, cirrhosis and hepatocellular carcinoma. In addition, for various groups of individuals as listed below, **Revac-B+®** immunization is an essential requirement:

- Healthcare personnel.
- Patients prone to infection due to unscreened or improperly tested blood transfusions.
- Hemophiliacs and patients on haemodialysis.
- Travellers to specified high endemic areas.
- Residents in high endemic areas.
- Persons in contact with infected sexual partners.
- Drug addicts.
- 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.

CONTRAINDICATIONS:

Revac-B+® is generally well tolerated. However the vaccine should not be administered or repeated to persons known to be hypersensitive to any of the components of the vaccine.

Avoid immunization during severe febrile illness.

DOSAGE:

As indicated in the composition an adult dose (20 µg/mL) is formulated for adults and children above 10 years of age.

Paediatric dose is (10 µg/0.5 mL) recommended for neonates, infants and children at and below 10 years of age.

IMMUNIZATION:

A. Primary immunization schedule:

An interval of 30 days is given between the administration of the FIRST and SECOND doses, followed by the THIRD dose 180 days after the first dose.

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:

- To neonates born to HBV infected mothers the recommended paediatric dose Schedule:

1st dose	on selected date
2nd dose	30 days after the first dose
3rd dose	60 days after the first dose
1st booster dose	1 year after the first dose

HBIg may also be given to compromised neonates on advice from the medical practitioner.

- To persons involuntarily exposed by accident to HBV infection: The schedule of immunization stated at (B) is recommended at paediatric dosage level for children and as adult dose for others.
- Immuno-compromised patients will require additional dosage as per schedule given:

1st dose of 40 µg (2mL)	-	on the first day
2nd dose of 40 µg (2mL)	-	30 days after the first dose
3rd dose of 40 µg (2mL)	-	60 days after the first dose
4th dose of 40 µg (2mL)	-	180 days after the first dose

METHOD OF ADMINISTRATION

Revac-B+® should be injected deep intramuscularly into the deltoid region in adults and in the antero-lateral aspect of the thigh in neonates, infants and young children.

Revac-B+® should NOT be injected into the gluteal muscle. This route of administration may result in lower immune response. Under no circumstance **Revac-B+®** should be given intravenously.

PRECAUTIONS:

It is suggested that the 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, may be kept readily available in case of area anaphylactic reactions due to the vaccine.

While using the multi-dose vial, care must be taken to use separate sterile syringes and needles for the administration of every dose. Used multi-dose vial that contains remaining vaccine must be stored at the recommended storage temperature and reexamined carefully prior to reuse. A multi-dose vial 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 the following conditions are met.

- 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

Before use, **Revac-B+®** should be well shaken to obtain a uniform, whitish translucent suspension. Vaccine should be visually checked for the presence of any particulate matter or other coloration, if any, prior to its administration. If in doubt, do not use the contents of the vial.

Revac-B+® can be administered at the same time as BCG, DPT, OPV and Measles vaccines that are extensively used in the Universal Programme of Immunization (UPI), worldwide. **Revac-B+®** should always be administered at a different injection site in the event of its use along with UPI vaccines.

Revac-B+® Should not be mixed with other vaccines.

NOTE: Because of the long incubation for hepatitis-B virus to manifest the symptoms, some subjects may receive the vaccine while the infection stays unrecognized. In such cases, the vaccine may not prevent the onset of hepatitis due to hepatitis - B virus.

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

ADVERSE REACTIONS:

Revac-B+® has proven low reactogenicity and is well tolerated. Open and comparative trials did not show adverse reactions in the vaccines.

Inflammation at the site of injection or a febrile reaction may be observed in some subjects.

In rare cases of post-vaccinal hypersensitivity, the common symptoms that are quickly recognised by the physician are dizziness, headache, nausea, abdominal pain, rash, pruritis, urticaria, arthralgia, myalgias and similar associated symptoms and side effects.

Strict adherence to the above mentioned precautions is advised to avoid untoward reactions.

PREGNANT AND LACTATING MOTHERS: Routine vaccination of pregnant women with recombinant Hepatitis-B vaccine is not recommended due to inadequate data on its effects on the foetus. No contraindication was recorded for the use of the vaccine in lactating mothers. However the decision to immunize pregnant and lactating mothers may be taken by the physician in the context of case-specific high risk factors.

SAFETY, STABILITY AND POTENCY:

Revac-B+® contains highly purified HBsAg in a formulation that consistently conforms to pharmacopoeial standards.

Experimental data, both at the production and R&D laboratories, have shown the formulation to be stable and potent for 36 months at +2°C to +8°C.

Exposure of vaccine to higher temperatures at 37°C for 1 month & 45°C for 1 week did not result in the loss of its immunogenicity.

IMMUNOLOGICAL PROPERTIES:

In clinical trials, **Revac-B+®** induced specific antibodies in the vaccinees against hepatitis B virus. Three doses of **Revac-B+®** immunization elicited high protective humoral antibody levels in 92 to 98 per cent of the recipients.

PHARMACEUTICAL PARTICULARS:

Category	:	Active immunizing agent.
Pharmaceutical form	:	Suspension for injection.
Shelf life	:	3 years from the date of manufacture.
Storage	:	+2°C to +8°C.

SHAKE WELL BEFORE USE
DO NOT FREEZE. DISCARD IF FROZEN.
KEEP OUT OF REACH OF CHILDREN.

PRESENTATION:

Revac-B+® is presented in USP type 1 glass vial. The content upon storage may present a fine white deposit with a clear colourless supernatant. Once shaken the vaccine is slightly opaque.

Paediatric single dose	:	0.5 mL
Adult single dose	:	1.0 mL
Paediatric Multi-dose	:	2.5 mL
Paediatric Multi-dose	:	5.0 mL
Adult Multi-dose	:	10.0 mL

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Manufactured & Marketed by:

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Lead Innovation

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