

## Patient Product Information

### REVAC- B mcf<sup>®</sup>

(India's First Thiomersal-free Hepatitis-B Vaccine)

Generic name: [Hepatitis-B Vaccine, Recombinant]

Read this information with care before getting REVAC- B mcf<sup>®</sup>

#### 1. What is REVAC-B mcf<sup>®</sup> and what is it used for?

REVAC-B mcf<sup>®</sup> is a vaccine used to prevent Hepatitis B disease. Hepatitis B disease is a liver disease caused by Hepatitis B virus. Short-term illness or acute hepatitis B develops within the first 6 months after exposure to virus. Symptoms include fever, tiredness, loss of hunger, dark coloured urine, clay coloured stools, pain in the muscles, joints, stomach and jaundice (yellow skin or eyes). Long-term or chronic hepatitis B is a lifelong illness that can cause cirrhosis (scarring of the liver), liver failure and liver cancer. Transmission of the virus takes place via blood, semen or other body fluids. It may also spread from mother to child during birth, having sex, sharing needles and razor. Getting vaccinated is the best way to prevent hepatitis B.

#### 2. What are the important aspects to note before administering REVAC- B<sup>®</sup>?

Be sure to tell your doctor before getting vaccinated if:

- Subject had a life-threatening allergic reaction to the hepatitis B vaccine or any ingredient in the vaccine
- Subject is sick

#### 3. How is REVAC-B mcf<sup>®</sup> administered?

- REVAC-B mcf<sup>®</sup> vaccine can be administered intramuscularly in the anterolateral aspect of the thigh in neonates, infants, young children and into the deltoid region in adults
- As per the recommendation of Indian Academy of Pediatrics (IAP), Hepatitis B vaccine should be administered at: birth, 6 weeks, 10 weeks and 14 weeks
- Adults: An interval of 30 days between the administration of the FIRST and SECOND doses, followed by the THIRD dose 180 days after the first dose.

#### 4. What are the possible side effects from administering REVAC-B mcf<sup>®</sup>?

Common side effects are local swelling at the site of injection. Fever may be observed in some subjects.

## **5. What is the significance of Thiomersal?**

Thiomersal is a mercury-containing compound, which is used as a preservative in some vaccine manufacturing and production processes. It is known to prevent the growth of bacteria and fungus. Usually the compound is used as a preservative in multi-dose vials, to maintain vaccine free from contamination. Mercury can cause neuro-developmental disorder, in infants such as Autism, mental retardation, speech disorders and attention deficit diseases.

Vaccine advocacy bodies such as American Academy of Pediatrics, Center for Disease control and European Medicines Agency for Evaluation of Medicines for Human Use recommend preservative free or Thiomersal free vaccines. The childhood vaccines that used to contain Thimerosal as a preservative are now put into single-dose vials so that no preservative is necessary, thus making the vaccines Thiomersal free and safer.