Recombivax-HB is noninfectious viral vaccine derived from hepatitis B surface antigen (Hbxag) produced by a recombinant strain of yeast (no human blood products are used to make this vaccine). It is indicated for immunization against infection caused by all known subtypes of hepatitis B virus, but does not provide protection caused by other agents such as hepatitis A, D, C, or E viruses or other viruses known to infect the liver. It is contraindicated in persons hypersensitive to yeast (those who have a severe, immediate allergic reaction to molds, especially yeast). It is recommended for all persons who are or will be at increased risk of infection with hepatitis B virus, i.e., health care workers and custodial staff who may be exposed to the virus via blood or other patient specimens.

Recombivax HB is generally well tolerated. No serious adverse reactions attributed to the vaccine have been reported during the course of clinical trials nor have any serious hypersensitivity reactions been reported. However, side effects such as redness, soreness and tenderness at injection site; fatigue/weakness; headache; fever (≥ 100 degrees F) and malaise are known to occur. Rash, nausea and joint pain have also been reported.

Since animal reproductive studies have not been conducted with Recombivax HB, it is not known whether it can cause fetal harm or affect reproduction capacity. Therefore, Recombivax HB should be given to a pregnant woman only if clearly needed. Additionally, it has not been determined whether this vaccine is excreted in human milk.

Vaccination consists of three injections according to the following schedule:

1st dose - elected date
2nd dose - 1 month later
3rd dose - 6 months after initial immunization

THE SERIES IS NOT CONSIDERED COMPLETE NOR IS OPTIMUM PROTECTION ACHIEVED UNTIL ALL 3 INJECTIONS HAVE BEEN RECEIVED.

Presently, the duration of protection effect is unknown and the need for booster doses is not yet defined, but as more information becomes available, the public will be informed.

Reference: Merck Sharp & Dohme