Hepatitis B Vaccine (rDNA) IP

Revac-B®

PRECAUTIONS

Common names include: PreVac-B®

Revac-B® is a single component, purified, recombinant human hepatitis B surface antigen (HBsAg), produced by recombinant DNA technology in Chinese hamster ovary (CHO) cells. The vaccine is a highly effective, highly purified, highly stable, low-pyrogenic product formulated with a preservative and adsorbent to enhance antigenicity and provide appropriate storage and handling conditions.

Reservations Required: By vacine manufacturer.

Revac-B® is contraindicated in patients with a known hypersensitivity to any component of the vaccine.

Pregnancy and Lactation

Revac-B® is contraindicated for use in patients with a known hypersensitivity to any component of the vaccine.

REACtIONS

Local and Systemic Reactions

Local reactions include pain, redness, and swelling at the injection site. Systemic reactions include malaise, fever, headache, nausea, vomiting, diarrhea, and myalgias.

Local reactions may occur at the injection site, generally within 24 hours of injection. Systemic reactions may occur within 48 hours of injection.

Immunogenicity

Revac-B® is highly immunogenic and induces a high level of immune response against hepatitis B surface antigen (HBsAg).

Efficacy

Revac-B® is highly efficacious in preventing hepatitis B infection and has been shown to provide long-term protection against infection.

ARTWORK APPROVAL

Product: Revac-B®
Name of the artwork: Package Insert
Market: Domestic
Artwork code: 51PID.04
Change control No: CC/QAO/18017
Item code: 140001520

Date: 14-07-2018
Specs: Revac-B®
Product: Package insert art work for Domestic
Colors: CMYK/Pantone
Back

Front

Canvas backing: 940 Black C

QA - RA

Corp comm

Packing Incharge

HOD - QC

HOD - Production

Marketing (Export / Domestic)

HOD - QAO