



Hepatitis B Vaccine Information Sheet and Consent Form

What is Hepatitis B?

Hepatitis B is a viral infection caused by the Hepatitis B Virus (HBV). Most people with Hepatitis B recover completely; 5 -10 % become chronic carriers of the virus. Most carriers have no symptoms but can continue to transmit disease to others. Others may develop chronic active hepatitis and cirrhosis of the liver. The virus also appears to be a causative factor in the development of liver cancer. Immunization against Hepatitis B can prevent acute hepatitis, reduce sickness and death from chronic hepatitis, cirrhosis and liver cancer.

Symptoms of Hepatitis

You may have the disease, or have had it in the past, and not have any symptoms, but most people have some of the following:

- mild fever
- tiredness
- headache
- upset stomach
- dark urine
- yellowing of the skin
- yellowing of whites of the eyes
- pain in the upper right abdomen

How do you get Hepatitis B?

You get Hepatitis B primarily through contact with the blood or body secretions of persons who are infected with the Hepatitis B virus. Additional ways of contracting Hepatitis B are through:

- blood transfusions
- sharing needles used for IV drug use
- exposure to contaminated needles and dental equipment in the third world, and
- sexual contact with persons carrying the virus.

A Hepatitis B carrier usually does not experience symptoms of the disease, but carries the virus in their blood and other body fluids. Some people who have Hepatitis B disease continue to carry this virus after recovery from the acute illness.

General Information

Items soaked with an infected person's blood should be disposed of or soaked in a 10% solution of household laundry bleach for one hour. The solution can be made by mixing 1 part of bleach with 9 parts of water.

Spills of blood or other body fluids should be cleaned up with soap and water, and the above water and bleach mixture. This should be left on the surface for 10 minutes. Gloves should be worn when cleaning up blood or body fluids, and when using the bleach mixture.

Engerix B Vaccine Information sheet

Hepatitis B vaccine is now available in a form that is not derived from human serum. The immunizations involve 3 intramuscular injections over a period of 2 or 6 months. We will be using Engerix B, produced by SmithKline Beecham Pharmaceuticals. The vaccine is 95% effective in healthy adults and may offer protection from the Hepatitis B virus for a minimum of 10 years.

Engerix B Hepatitis B Vaccine is a recombinant non-infectious vaccine derived from Hepatitis B surface antigen (HBsAg) produced in yeast cells. A portion of the Hepatitis B virus gene, coding HBsAg, is cloned into yeast, and the vaccine for Hepatitis B is produced from cultures of this recombinant yeast strain. The vaccine against Hepatitis B, prepared from recombinant yeast cultures, is free of association with human blood or blood products.

Adverse Reactions

Engerix B is generally well tolerated. No serious adverse reactions attributable to the vaccine have been reported during the course of clinical trials. No serious hypersensitivity reactions have been reported.

The following adverse reactions were reported:

Incidence equal to or greater than 1% of injections

- **Local reaction (injection site):** incidence 1 - 10% of injections - pain, redness
- **Body as a whole:** fever
- **Nervous system:** headache, dizziness

Incidence <1% of injections

- **Local reactions of injection site:** pain, itching, bruising
- **Body as a whole:** sweating, fatigue, chills, weakness, flushing, tingling
- **Cardiovascular system:** low blood pressure
- **Respiratory system:** Influenza-like symptoms, cold symptoms
- **Gastrointestinal System:** nausea, abdominal pain/cramps, vomiting, constipation, diarrhea, poor appetite.
- **Lymphatic system:** swollen glands
- **Musculoskeletal system:** muscle and/or joint pain
- **Skin and Appendages:** rash, itching, hair loss
- **Nervous system:** insomnia, irritability, agitation, sleepiness