



Skaneateles Fire Department

INFORMATION ON THE HEPATITIS B VACCINE

The Disease

Hepatitis means inflammation of the liver. Hepatitis B, which is a viral infection, is one of multiple causes of hepatitis. Most people with Hepatitis B recover completely, but approximately 5-50% become chronic carriers; 1-2% die of fulminant hepatitis. In the group of chronic carriers, many have no symptoms and appear well, yet can transmit the virus to others. Others may develop a variety of symptoms and liver problems varying from mild to severe (chronic persistent hepatitis, chronic active hepatitis, cirrhosis and liver failure). There is also an association between Hepatitis B virus and hepatoma (a form of liver cancer).

Hepatitis B virus can be transmitted by contact with body fluids including blood (including contaminated needles), semen, tears, saliva, urine, breast milk, and vaginal secretions. Health workers are at high risk of acquiring Hepatitis B because of frequent contact with blood or potentially contaminated body fluids and, therefore, vaccine is recommended to prevent the illness.

The Vaccine

"Engerix-B" (Hepatitis B Vaccine [Recombinant]) is a noninfectious Recombinant DNA Hepatitis B Vaccine. Clinical studies have shown that after three doses 96% of health adults have been seroprotected.

Persons with immune system abnormalities, such as dialysis patients, have less response to the vaccine, but over 67% of those receiving it do develop antibodies. If you have immune deficiency problems, you should obtain a written release from your physician.

Dosing Schedules

Three doses of Hepatitis B Vaccine are needed to confer protection. "Engerix-B" is administered at 0, 1, and 6 months or alternatively at a 0, 1, and 2 month regimen. This regimen is designated for protection of individuals at immediate risk of Hepatitis B infection -- those recently exposed to the virus (including needlestick exposure), certain travelers to high-risk areas, and neonates born of infected mothers. Studies have shown that 99% of subjects vaccinated with the 0, 1, 2 month dosing regimen have developed protective antibody titers by month 3.

Adverse Reactions

"Engerix-B" (Hepatitis B Vaccine {Recombinant}) is generally well tolerated. During clinical studies involving over 10,000 individuals distributed over all age groups, no serious adverse reactions attributable to vaccine administration were reported. As with any vaccine, however, it is possible that expanded commercial use of the vaccine could reveal rare adverse reactions not observed in clinical studies. The most frequently reported adverse reactions were injection-site soreness, fatigue, induration, erythema, swelling, fever, headache, and dizziness. Other more serious adverse reactions have occurred infrequently. If you have any questions about Hepatitis B or about "Engerix-B", please ask.

Contraindications

Hypersensitivity to yeast or any other component of the vaccine (e.g.: formalin or mercury derivatives) is a contraindication for use of the vaccine.

Warnings

Patients experiencing hypersensitivity after an "Engerix-B" (Hepatitis B Vaccine [Recombinant]) injection should not receive further injections of "Engerix-B" (see [Contraindications](#)).

Hepatitis B has a long incubation period. Hepatitis B Vaccination may not prevent Hepatitis B infection in individuals who have an unrecognized Hepatitis B infection at the time of vaccine administration. Additionally, small percentages of healthy people do not respond to the vaccine and do not develop an immunity to the HBV.

Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with "Engerix-B." It is also not known whether "Engerix-B" can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. "Engerix-B" should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether "Engerix-B" is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when "Engerix-B" is administered to a nursing woman.

Approval from Physician

Approved for Vaccination: _____ Yes _____ No

Physician's Signature

Date

CONSENT FORM

I, _____, have read the above statement about Hepatitis B and the Hepatitis B Vaccine, "Engerix-B". I have been provided with updated information and have had the opportunity to ask questions about the benefits and risks of Hepatitis B Vaccination. I understand that there is no guarantee that I will become immune and that there is a possibility that I will experience an adverse side effect from the vaccine.

For Women

I have been advised that studies have not been conducted to determine the effect of the vaccine on a developing fetus. Therefore, the safety of the vaccine is not known on the developing fetus. I have opted to receive the Hepatitis B vaccine, and hereby consent to the administration of three doses of the Hepatitis B Vaccine over the next 6 months.

Signature of the Recipient

Date

DECLINE TO ACCEPT HEPATITIS B VACCINE

I have read the information provided by the University Medical Center about Hepatitis B and the Hepatitis B Vaccine, "Engerix-B". I have had an opportunity to ask questions, understand the benefits and risks of the Hepatitis B Vaccine, and do not wish to receive this vaccine. I request that it not be given to me.

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Signature of the Recipient

Date

Employee _____

Employee _____

Hepatitis B Vaccination Status

(To be maintained by the providing medical facility.)

Please check all that apply:

1. Hepatitis B Vaccination Series received _____

a. Date and Location of Administration of the Vaccine/Booster:

(1) _____

(2) _____

(3) _____

(4) _____

(5) _____

(6) _____

2. Antibody Testing indicates employee is immune to Hepatitis B _____

A. Date and Location of Testing

(1) _____

(2) _____

(3) _____

(4) _____

(5) _____

(6) _____

3. Hepatitis B vaccine is contraindicated for medical reasons _____

4. Employee/student declines the vaccination series (attach signed statement) _____

Physician

Date

Employee Information



Skaneateles Fire Department

INFORMATION ON THE HEPATITIS B VACCINE

The Disease

Hepatitis means inflammation of the liver. Hepatitis B, which is a viral infection, is one of multiple causes of hepatitis. Most people with Hepatitis B recover completely, but approximately 5-50% become chronic carriers; 1-2% die of fulminant hepatitis. In the group of chronic carriers, many have no symptoms and appear well, yet can transmit the virus to others. Others may develop a variety of symptoms and liver problems varying from mild to severe (chronic persistent hepatitis, chronic active hepatitis, cirrhosis and liver failure). There is also an association between Hepatitis B virus and hepatoma (a form of liver cancer).

Hepatitis B virus can be transmitted by contact with body fluids including blood (including contaminated needles), semen, tears, saliva, urine, breast milk, and vaginal secretions. Health workers are at high risk of acquiring Hepatitis B because of frequent contact with blood or potentially contaminated body fluids and, therefore, vaccine is recommended to prevent the illness.

The Vaccine

"Engerix-B" (Hepatitis B Vaccine [Recombinant]) is a noninfectious Recombinant DNA Hepatitis B Vaccine. Clinical studies have shown that after three doses 96% of health adults have been seroprotected.

Persons with immune system abnormalities, such as dialysis patients, have less response to the vaccine, but over 67% of those receiving it do develop antibodies. If you have immune deficiency problems, you should obtain a written release from your physician.

Dosing Schedules

Three doses of Hepatitis B Vaccine are needed to confer protection. "Engerix-B" is administered at 0, 1, and 6 months or alternatively at a 0, 1, and 2 month regimen. This regimen is designated for protection of individuals at immediate risk of Hepatitis B infection -- those recently exposed to the virus (including needlestick exposure), certain travelers to high-risk areas, and neonates born of infected mothers. Studies have shown that 99% of subjects vaccinated with the 0, 1, 2 month dosing regimen have developed protective antibody titers by month 3.

Adverse Reactions

"Engerix-B" (Hepatitis B Vaccine {Recombinant}) is generally well tolerated. During clinical studies involving over 10,000 individuals distributed over all age groups, no serious adverse reactions attributable to vaccine administration were reported. As with any vaccine, however, it is possible that expanded commercial use of the vaccine could reveal rare adverse reactions not observed in clinical studies. The most frequently reported adverse reactions were injection-site soreness, fatigue, induration, erythema, swelling, fever, headache, and dizziness. Other more serious adverse reactions have occurred infrequently. If you have any questions about Hepatitis B or about "Engerix-B", please ask.

Contraindications

Hypersensitivity to yeast or any other component of the vaccine (e.g.: formalin or mercury derivatives) is a contraindication for use of the vaccine.

Warnings

Patients experiencing hypersensitivity after an "Engerix-B" (Hepatitis B Vaccine [Recombinant]) injection should not receive further injections of "Engerix-B" (see Contraindications).

Hepatitis B has a long incubation period. Hepatitis B Vaccination may not prevent Hepatitis B infection in individuals who have an unrecognized Hepatitis B infection at the time of vaccine administration. Additionally, small percentages of healthy people do not respond to the vaccine and do not develop an immunity to the HBV.

Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with "Engerix-B." It is also not known whether "Engerix-B" can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. "Engerix-B" should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether "Engerix-B" is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when "Engerix-B" is administered to a nursing woman.