

## ACKNOWLEDGMENT OF HEPATITIS B VACCINE POLICY

**THERE ARE OVER 3 Million** people infected with Hepatitis B Virus (HBV) worldwide. The current vaccine, Food and Drug Administration approved since 1981, is made from yeast and is one of the safest vaccines available and can provide you with protection. No live virus is present in the vaccine so you **can not** get the virus through the vaccine.

Side effects that have been reported from the vaccine include soreness, swelling and redness at the injection site. Possible systemic symptoms are from headache, dizziness, nausea, vomiting, slight fever, transient malaise, myalgia and cold-like symptoms to life threatening.

Due to possible reactions to this vaccine, recipients must remain in the general vicinity of where this service is provided, for at least 20 minutes after administration of the vaccine, in order for the healthcare provider to assist with any emergency medical care, should it be needed.

**INDIVIDUALS WITH KNOWN ALLERGIES OR SENSITIVE** to Thimerosal, which is also known to be in products used to disinfect the skin prior to surgeries, and those individuals with reactions to prior HBV immunizations, should refer to their Physician prior to receiving this HBV Series.

**HEALTHY ADULTS AND CHILDREN FROM AGE TEN (10)**, receive the Engerix B Series in three (3) intramuscular doses of 1 ml. In order to ensure proper immunization, the following schedule must be followed.

**SCHEDULE:** 1<sup>st</sup> Dose received

Thirty (30) days later, 2<sup>nd</sup> Dose should be received

Six months after 1<sup>st</sup> dose; 3<sup>rd</sup> Dose should be received

### CONTRAINDICATIONS

Hypersensitivity to yeast or any other component of the vaccine is a contraindication for use of the vaccine.

**WARNINGS:** Patients experiencing hypersensitivity after Hepatitis B Vaccine should not receive further injections (see contraindications). Hepatitis B has a long incubation period. Hepatitis B vaccinations may not prevent Hepatitis B infection individual who have an unrecognized Hepatitis B infection at the time of vaccine administration. Additionally, it may not prevent infection in individuals who do not achieve protection antibody titers.

**PRECAUTIONS:** As with any percutaneous vaccine, epinephrine should be available for use in case of anaphylaxis or anaphylactoid reaction. As with any vaccine, administration should be delayed if possible, in persons with any febrile illness or active infection.

**PREGNANCY:** Pregnancy Category C: Animal reproduction studies have not been conducted. It is also known whether vaccine can cause fetal harm when administered to a pregnant woman or can affect reproductive ability. Therefore, vaccine should be given to a pregnant woman, only if clearly needed.

**NURSING MOTHERS:** It is not known whether vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when vaccine is administered to a nursing woman.

**ADVERSE REACTIONS:** Hepatitis B vaccine is generally well tolerated. During clinical studies involving over 10,000 individuals distributed over all age group, 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. Using a symptom checklist, the most frequently reported adverse reactions were injection site soreness (22%) and fatigue (14%). Other reactions are listed below:

Fever, Headaches, Dizziness, Ecchymosis, Sweating, Chills	<u>Muscular Skeletal:</u> pain, stiffness in arms, shoulders, neck and back pain
<u>Cardiovascular:</u> tachycardia, palpitations	<u>Skin and Appendages:</u> rash, eczema, herpes zoster, erythema
<u>Respiratory:</u> influenza, URI, broncho spasm	nodosum, urticaria, petechia
<u>GI:</u> nausea anoxia, abdominal pain, cramps, vomiting, diarrhea	<u>Nervous System:</u> insomnia, agitation, irritability, somnolence,
<u>Lymph System:</u> lymphadenopathy	migraine headache, syncope neuropathy, peresthenia, Gallium-Barre and Bells palsy
<u>Hemolytic:</u> thrombocytopenia	<u>Hypersensitivity:</u> anaphylaxis, orythemia, multiforme including Steven Johnson Syndrome

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HEPATITIS B VACCINE POLICY**

TDY has provided information regarding the efficacy, safety and administration procedure for the Hepatitis B vaccination series and has offered to pay for the series. I certify that I have read and understand the policy and release TDY from all liability for any adverse reactions that may result from this Hepatitis B vaccine series.

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 cost to myself.

*Please check one of the following:*

**HEPATITIS B VACCINATION DECLINATION**

**I decline the Hepatitis B vaccination series offered by TDY 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. I release TDY from all liability regarding the contraction of Hepatitis B in the performance of my job duties.

Employee Name – PRINT: \_\_\_\_\_

Employee Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**I decline the Hepatitis B vaccination series because I have already been vaccinated for Hepatitis B within the last ten (10) years. I understand that I must provide documentation of my previous Hepatitis vaccination to TDY upon request.**

Employee Name – PRINT: \_\_\_\_\_

Employee Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**HEPATITIS B VACCINATION ACCEPTANCE**

**I accept the Hepatitis B vaccination series offered by TDY.**

Employee Name – PRINT: \_\_\_\_\_

Employee Signature: \_\_\_\_\_

Date: \_\_\_\_\_