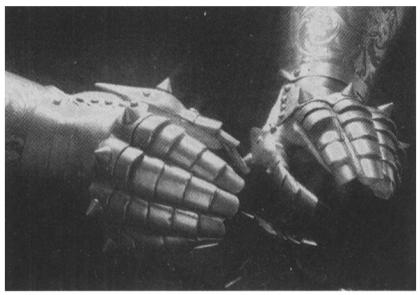

HYPERHEP™
Hepatitis B Immune Globulin (Human)

Summary of Prescribing Information

DESCRIPTION Hepatitis B Immune Globulin (Human)—HyperHep™—is a sterile solution of immunoglobulin (15-18% protein) which is prepared by cold alcohol fractionation from pooled venous plasma of individuals with high titers of antibody to the hepatitis B surface antigen (anti-HBs). The product is stabilized with 0.3 M glycine and contains 1:10,000 Thimerosal (a mercury derivative) as a preservative. The solution has a pH of 6.8 ±0.4 adjusted with sodium carbonate. Each vial contains anti-HBs antibody equivalent to or exceeding the potency of anti-HBs in a U.S. reference hepatitis B immune globulin (Bureau of Biologics, FDA). The product is prepared from units of human plasma that have been tested and found non-reactive for hepatitis B surface antigen.

INDICATIONS Hepatitis B Immune Globulin (Human)—HyperHep™—is indicated for post-exposure prophylaxis following either parenteral exposure, e.g., by accidental "needle-stick," or direct mucous membrane contact (accidental splash), or oral ingestion (pipetting accident) involving HB_SAg positive materials such as blood, plasma or serum. Use of hepatitis B immune globulin in other situations has been and continues to be evaluated, but there are not sufficient data at present on effectiveness, dosage and schedule for any other uses to be included as definite indications. There is currently some controversy over whether immune globulin containing a low or high anti-HBs titer is preferable in these other situations.

CONTRAINDICATIONS There are no specific contraindications for hepatitis B immune globulin. No adverse reactions have been seen in individuals with pre-existing hepatitis B surface antigen although data regarding this occurrence are limited.

WARNING Hepatitis B Immune Globulin (Human)—HyperHep™—should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immune globulin preparations.

PRECAUTIONS GENERAL Hepatitis B Immune Globulin (Human) should *not* be administered intravenously because of the potential for serious reactions. Injections should be made intramuscularly, and care should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel.

SPECIAL INSTRUCTIONS Although systemic reactions to immune globulin preparations are rare, epinephrine should be available.

CLINICALLY SIGNIFICANT PRODUCT INTERACTIONS Live virus vaccines such as measles vaccine should not be given close to the time of hepatitis B immune globulin administration because antibodies in the globulin preparation may interfere with the immune response to the vaccination. No interactions with other products are known.

PREGNANCY No studies have been conducted in pregnant patients. Clinical experience with other immunoglobulin preparations administered during pregnancy suggests that there are no known adverse effects on the fetus from immune globulins per se, but there are no reported studies indicating whether or not such adverse effects occur.

ADVERSE REACTIONS Local pain and tenderness at the injection site, and urticaria and angioedema may occur; anaphylactic reactions, although rare, have been reported following the injection of human immune globulin preparations.

OVERDOSE Although no data are available, clinical experience with other immunoglobulin preparations suggests that the only manifestations would be pain and tenderness at the injection site.

DOSE AND ADMINISTRATIONS The recommended dose is 0.06 ml per kilogram of body weight; the usual adult dose is 3 to 5 ml. The appropriate dose should be administered as soon after exposure as possible (preferably within 7 days) and repeated 28-30 days after exposure. Hepatitis B Immune Globulin (Human) is administered intramuscularly, preferably in the gluteal or deltoid region.

CAUTION Federal (U.S.A.) law prohibits dispensing without prescription.

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IC INFECTION CONTROL

LETTERS TO THE EDITOR

To the Editor:

Nursing service is in the process of rewriting a number of procedures. The technique for obtaining a lochia specimen and a vaginal cuff specimen is being looked at again. I have several questions. What technique should be used? Should a speculum be used and if so is this a nursing procedure? What are the real values if our pathology lab cannot do anaerobic pathogenic studies?

I will appreciate any assistance you can give me with these questions.

Sylvia M. Abney, RN
Infection Control Officer
King's Daughters Hospital
Brookhaven, Mississippi

This letter was referred to Charles Osterman who, with Willie Andersen, wrote the following reply.

There are several methods available for obtaining a lochia specimen. One method uses a "triple lumen cannula," introduced through the cervix into the uterus, where a sample of the lochia may then be aspirated for culture. Alternate methods are to use a "novak" curette designed for this purpose, or to cleanse the cervix with a povidone-iodine solution, dilating the cervix and aspirating material for culture with a syringe.

To obtain a vaginal cuff culture, the reapproximated edges of the cuff, (where the cervix was) are dilated and any material present in that cavity, which may sometimes be pus, is aspirated and sent for culture. The aspirated material generally is placed in standard holding media for transport to the lab.

A speculum should be used for these procedures, which may well be performed by OB/GYN nursing personnel in most hospital settings. This may not always be the case in private practice, where this procedure is usually performed by the physician.

Cultures of the lochia and vaginal cuff should be obtained anytime an infective process is suspected, to determine the specific infecting organism(s), even though the lab may not be equipped to handle anaerobic cultures. The presence of *Streptococcus* is of major concern following Cesarean section; the presence of *E. coli* or other gram-negative aerobic organisms may be significant, too, although not of as great a significance as *Streptococcus* organisms. Additionally, simplified means for handling anaerobic cultures are rapidly becoming more widely available, and more laboratories are developing such capabilities for routine use. However, cultures should be performed in any event, even if only for aerobic pathogens.

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