

PRODUCT MONOGRAPH

**HyperHEP B® S/D**

Hepatitis B Immune Globulin (Human)

*Solvent/Detergent Treated*

Injectable Solution,  $\geq 220$  IU/mL

Manufacturer's Standard

Passive Immunizing Agent

Manufactured by:  
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# HyperHEP B® S/D

Hepatitis B Immune Globulin (Human)

*Solvent/Detergent Treated*

## PART I: HEALTH PROFESSIONAL INFORMATION

### SUMMARY PRODUCT INFORMATION

Table 1 – Product Information Summary

Route of Administration	Dosage Form, Strength	Clinically Relevant Nonmedicinal Ingredients
Intramuscular injection	Injectable solution, ≥220 IU/mL	<i>For a complete listing see <a href="#">DOSAGE FORMS, COMPOSITION AND PACKAGING</a> section.</i>

### DESCRIPTION

HyperHEP B® S/D (Hepatitis B Immune Globulin [Human]) treated with solvent/detergent is a sterile solution of hepatitis B hyperimmune immune globulin for intramuscular administration; it contains no preservative. HyperHEP B® S/D is prepared by cold ethanol fractionation from the plasma of donors with high titers of antibody to the hepatitis B surface antigen (anti-HBs). The immune globulin is isolated from solubilized Cohn fraction II. The fraction II solution is adjusted to a final concentration of 0.3% tri-n-butyl phosphate (TNBP) and 0.2% sodium cholate. After the addition of solvent (TNBP) and detergent (sodium cholate), the solution is heated to 30°C and maintained at that temperature for not less than 6 hours. After the viral inactivation step, the reactants are removed by precipitation, filtration and finally ultrafiltration and diafiltration. HyperHEP B® S/D is formulated as a 15-18% protein solution at a pH of 6.4-7.2 in 0.21-0.32 M glycine. The pH is adjusted with sodium carbonate. HyperHEP B® S/D is then incubated in the final container for 21-28 days at 20-27°C.

### INDICATIONS AND CLINICAL USE

The Canadian Immunization Guide recommends that hepatitis B prevention should include programs for active immunization of children, pre-exposure vaccination of high risk groups, and post-exposure passive immunization for those exposed to disease, particularly infants born to HBV-carrier mothers (1). Recommendations on post-exposure prophylaxis are based on available efficacy data and on the likelihood of future HBV exposure for the person requiring treatment. In all exposures, a regimen combining Hepatitis B Immune Globulin (Human) with hepatitis B vaccine will provide both short- and long-term protection, will be less costly than the

two-dose Hepatitis B Immune Globulin (Human) treatment alone and is the treatment of choice (2).

Administration of Hepatitis B Immune Globulin (Human) either preceding or concomitant with the commencement of active immunization with Hepatitis B vaccine provides for more rapid achievement of protective levels of hepatitis B antibody, than when the vaccine alone is administered (3). Rapid achievement of protective levels of antibody to hepatitis B virus may be desirable in certain clinical situations, as in cases of accidental inoculations with contaminated medical instruments (3). Administration of Hepatitis B Immune Globulin (Human) either 1 month preceding or at the time of commencement of a program of active vaccination with hepatitis B vaccine has been shown not to interfere with the active immune response to the vaccine (3).

HyperHEP B® S/D is indicated for post-exposure prophylaxis in the following situations, unless it is known, by testing within the 24 previous months or can be established within 48 hours that the patient has levels of pre-existing antibodies to hepatitis B virus surface antigen at greater than or equal to 10 IU/L.

#### **Acute Exposure to Blood Containing HBsAg**

After either parenteral exposure, e.g., by accidental “needlestick” or direct mucous membrane contact (accidental splash), or oral ingestion (pipetting accident) involving HBsAg-positive materials such as blood, plasma or serum. For inadvertent percutaneous exposure in patients unwilling to take the hepatitis B vaccine regimen, a regimen of two doses of Hepatitis B Immune Globulin (Human), one given after exposure and one a month later, is about 75% effective in preventing hepatitis B in this setting.

#### **Perinatal Exposure of Infants Born to HBsAg-positive Mothers**

Infants born to HBsAg-positive mothers are at risk of being infected with hepatitis B virus and becoming chronic carriers (2,4-6). This risk is especially great if the mother is HBeAg-positive (7-9). For an infant with perinatal exposure to an HBsAg-positive and HBeAg-positive mother, a regimen combining one dose of Hepatitis B Immune Globulin (Human) at birth with the hepatitis B vaccine series started soon after birth is 85%-95% effective in preventing development of the HBV carrier state (2,10). Regimens involving either multiple doses of Hepatitis B Immune Globulin (Human) alone or the vaccine series alone have 70%-90% efficacy, while a single dose of Hepatitis B Immune Globulin (Human) alone has only 50% efficacy (2,9).

#### **Sexual Exposure to an HBsAg-positive Person**

Sex partners of HBsAg-positive persons are at increased risk of acquiring HBV infection. Sexual partners of an acute case of hepatitis B should begin a hepatitis B vaccine series. For sexual exposure to a person with acute hepatitis B, a single dose of Hepatitis B Immune Globulin (Human) is 75% effective if administered within 2 weeks of last sexual exposure (2). The Canadian Immunization Guide indicates that the administration of Hepatitis B Immune Globulin

(Human) to a sexual assault victim should prevent the development of hepatitis B virus infection if the alleged assailant is HBsAg positive (1).

### **Household Exposure to Persons with Acute HBV Infection**

Since infants have close contact with primary care-givers and they have a higher risk of becoming HBV carriers after acute HBV infection, prophylaxis of an infant less than 12 months of age with Hepatitis B Immune Globulin (Human) and hepatitis B vaccine is indicated if the mother or primary care-giver has acute HBV infection (2).

### **CONTRAINDICATIONS**

- HyperHEP B® S/D should not be given to patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the [DOSAGE FORMS, COMPOSITION AND PACKAGING](#) section.
- In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, HyperHEP B® S/D should be given only if the expected benefits outweigh the risks.

### **WARNINGS AND PRECAUTIONS**

#### **Serious Warnings and Precautions**

- For intramuscular injection only. Do not give intravenously (see [WARNINGS AND PRECAUTIONS: General](#)).
- Products made from human plasma may contain infectious agents such as viruses (see [WARNINGS AND PRECAUTIONS: General](#)).

#### **General**

HyperHEP B® S/D 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.

Intramuscular injections are preferably administered in the anterolateral aspects of the upper thigh and the deltoid muscle of the upper arm. The gluteal region should not be used routinely as an injection site because of the risk of injury to the sciatic nerve. An individual decision as to which muscle is injected must be made for each patient based on the volume of material to be administered. If the gluteal region is used when very large volumes are to be injected or multiple doses are necessary, the central region **MUST** be avoided; only the upper, outer quadrant should be used (11).

**HyperHEP B® S/D is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. The risk that such**

products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some viral infections, particularly hepatitis C. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Grifols Canada Ltd. [1-866-482-5226].

The physician should discuss the risks and benefits of this product with the patient, before prescribing or administering to the patient.

### **Hypersensitivity**

HyperHEP B® S/D should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immune globulin preparations. Epinephrine should be available.

### **Special Populations**

#### ***Pregnant Women***

There is no experience of exposure in pregnancy during clinical trials. Animal reproduction studies have not been conducted with HyperHEP B® S/D. It is also not known whether HyperHEP B® S/D can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. HyperHEP B® S/D should be given to a pregnant woman only if clearly needed.

#### ***Pediatrics***

With the exception of neonates and infants up to 12 months of age (2), safety and effectiveness in the pediatric population have not been established.

### **Monitoring and Laboratory Tests**

None required.

## **ADVERSE REACTIONS**

### **Adverse Drug Reaction Overview**

Local pain and tenderness at the injection site, urticaria and angioedema may occur; anaphylactic reactions, although rare, have been reported following the injection of human immune globulin preparations (12).

## DRUG INTERACTIONS

### Drug-Drug Interactions

Table 2 – Established or Potential Drug-drug Interactions

Proper Name	Ref	Effect	Clinical Comment
Live viral vaccines	CT/T	Although administration of Hepatitis B Immune Globulin (Human) did not interfere with measles vaccination (13) it is not known whether Hepatitis B Immune Globulin (Human) may interfere with other live virus vaccines.	Immunization with live vaccines, other than measles vaccination, should not be given within 3 months after HyperHEP B® S/D administration.

Legend: C=Case Study; CT=Clinical Trial; T=Theoretical

Hepatitis B vaccine may be administered at the same time as HyperHEP B® S/D, but at a different injection site, without interfering with the immune response (3). No interactions with other products are known.

### Drug-Food Interactions

No interactions are known

### Drug-Herb Interactions

No interactions are known

### Drug-Laboratory Interactions

No interactions are known

## DOSAGE AND ADMINISTRATION

### Dosing Considerations

The Canadian Immunization Guide recommends in general that Hepatitis B Immune Globulin (Human) be given along with a regimen of hepatitis B vaccine (1). Consult the hepatitis B vaccine package insert for dosage information concerning that product.

### Recommended Dose and Dosage Adjustment

#### *Acute Exposure to Blood Containing HBsAg*

Table 3 summarizes prophylaxis for percutaneous (needlestick or bite), ocular, or mucous-membrane exposure to blood according to the source of exposure and vaccination status of the exposed person. For greatest effectiveness, passive prophylaxis with Hepatitis B Immune Globulin (Human) should be given as soon as possible after exposure (its value beyond 7 days of exposure is unclear). As soon as possible and within 48 hours of exposure, for adults, an

injection of 0.06 mL/kg of body weight should be administered intramuscularly (see [WARNINGS AND PRECAUTIONS: General](#)). Treatment with Hepatitis B Immune Globulin (Human) is more effective if combined with a hepatitis B vaccine regimen given immediately but at a different site (1). Consult hepatitis B vaccine package insert for dosage information regarding that product. There is no established dosage for children.

**Table 3 – Course of Action Following Percutaneous (“Needlestick”) or Mucosal Exposure to Hepatitis B Virus (adapted from 1)**

Exposed Person		Source <sup>a</sup>		
Vaccination Status	Anti-HBs Level	HBsAg Positive	Unknown Status	
			High Risk	Low Risk
Vaccinated	≥10 IU/L documented within the previous 2 years	no action necessary	no action necessary	no action necessary
	≥10 IU/L documented more than 2 years ago	assess anti-HBs level; if ≥10 IU/L, no action; if <10 IU/L, give single booster of vaccine	assess anti-HBs level; if ≥10 IU/L, no action; if <10 IU/L, give single booster of vaccine	no action necessary
	known non-responder (anti-HBs level <10 IU/L after vaccination)	HBIG <sup>b,c,d</sup>	HBIG <sup>c,d</sup>	no action necessary <sup>d</sup>
	level unknown and unable to be determined within 48 hours	HBIG <sup>c</sup> + single booster of vaccine	single booster of vaccine ± HBIG <sup>c</sup>	no action necessary
Unvaccinated	≥10 IU/L	no action necessary	no action necessary	no action necessary
	level unknown at 48 hours or <10 IU/L	HBIG <sup>c</sup> + full vaccine course	full vaccine course ± HBIG <sup>c</sup>	full vaccine course

- a If source is known to be HBsAg negative, no action is required unless exposed person requires initiation of vaccination series.
- b Hepatitis B Immune Globulin (Human)
- c Hepatitis B Immune Globulin (Human) 0.06 mL/kg preferably given within 48 hours of exposure. Efficacy decreases with time and is unknown after 7 days.
- d If exposed person has received only three vaccine doses, an additional three-dose series may be administered.

### ***Prophylaxis of Infants Born to HBsAg and HBeAg Positive Mothers***

Efficacy of prophylactic Hepatitis B Immune Globulin (Human) in infants at risk depends on administering Hepatitis B Immune Globulin (Human) on the day of birth. It is therefore vital that HBsAg-positive mothers be identified before delivery.

Hepatitis B Immune Globulin (Human) (0.5 mL) should be administered intramuscularly (IM) to the newborn infant after physiologic stabilization of the infant and preferably within 12 hours of birth. Hepatitis B Immune Globulin (Human) efficacy decreases markedly if treatment is delayed beyond 48 hours. Hepatitis B vaccine should be administered as per the package insert of the manufacturer. Hepatitis B vaccine should be administered, starting the regimen within 7 days of



birth, and may be given concurrently with Hepatitis B Immune Globulin (Human), but at a different site. If administration of the first dose of hepatitis B vaccine is delayed for as long as 3 months, then a 0.5 mL dose of Hepatitis B Immune Globulin (Human) should be repeated at 3 months. If hepatitis B vaccine is refused, the 0.5 mL dose of Hepatitis B Immune Globulin (Human) should be repeated at 3 and 6 months. Hepatitis B Immune Globulin (Human) administered at birth should not interfere with oral polio and diphtheria-tetanus-pertussis vaccines administered at 2 months of age (10).

***Sexual Exposure to an HBsAg-positive Person***

All susceptible persons whose sex partners have acute hepatitis B infection should receive a single dose of Hepatitis B Immune Globulin (Human) (0.06 mL/kg) and should begin the hepatitis B vaccine series if prophylaxis can be started within 14 days of the last sexual contact or if sexual contact with the infected person will continue (see Table 4 below). Administering the vaccine with Hepatitis B Immune Globulin (Human) may improve the efficacy of postexposure treatment. The vaccine has the added advantage of conferring long-lasting protection (2).

**Table 4 – Recommendations for Postexposure Prophylaxis for Sexual Exposure to Hepatitis B (adapted from 1)**

HBIG <sup>a</sup>		Vaccine	
Dose	Recommended timing	Dose	Recommended timing
0.06 mL/kg IM <sup>b</sup>	Single dose within 14 days of last sexual contact	See package insert of that product for dosage and administration	First dose at time of HBIG <sup>a</sup> treatment <sup>c</sup>

- a HBIG - Hepatitis B Immune Globulin (Human)
- b Hepatitis B Immune Globulin (Human) 0.06 mL/kg preferably given within 48 hours of exposure. Efficacy decreases with time and is unknown after 7 days.
- c the first dose can be administered the same time as the HBIG dose but at a different site; subsequent doses should be administered as recommended for specific vaccine

***Household Exposure to Persons with Acute HBV Infection***

Prophylactic treatment with a 0.5 mL dose of Hepatitis B Immune Globulin (Human) and hepatitis B vaccine is indicated for infants 12 months of age who have been exposed to a primary care-giver who has acute hepatitis B. Prophylaxis for other household contacts of persons with acute HBV infection is not indicated unless they have had identifiable blood exposure to the index patient, such as by sharing toothbrushes or razors. Such exposures should be treated like sexual exposures. If the index patient becomes an HBV carrier, all household contacts should receive hepatitis B vaccine (2).

**Administration**

Hepatitis B Immune Globulin (Human) may be administered at the same time (but at a different site), or up to 1 month preceding hepatitis B vaccination without impairing the active immune response from hepatitis B vaccination (9).

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

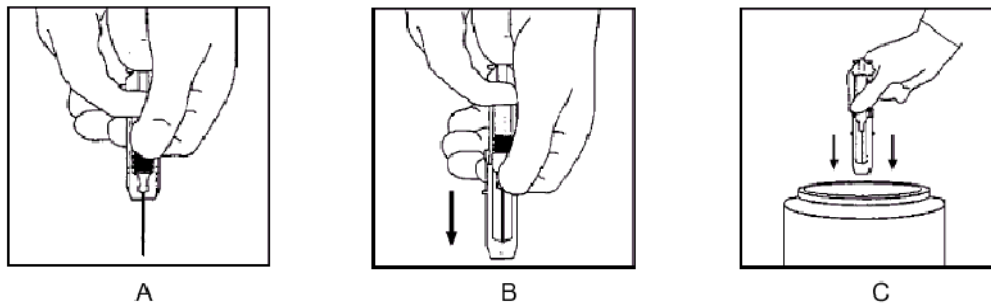
HyperHEP B® S/D is to be administered intramuscularly. Do not inject intravenously. Discard any unused remaining material immediately into biohazardous waste. HyperHEP B® S/D is supplied as single use syringe and vials.

### ***Directions for Syringe Usage***

HyperHEP B® S/D is supplied with a syringe and an attached UltraSafe® Needle Guard for your protection and convenience. Please follow instructions below for proper use of syringe and UltraSafe® Needle Guard.

1. Remove the prefilled syringe from the package. Lift syringe by barrel, **not** by plunger.
2. Twist the plunger rod clockwise until the threads are seated.
3. With the rubber needle shield secured on the syringe tip, push the plunger rod forward a few millimeters to break any friction seal between the rubber stopper and the glass syringe barrel.
4. Remove the needle shield and expel air bubbles. (Do not remove the rubber needle shield to prepare the product for administration until immediately prior to the anticipated injection time.)
5. Proceed with hypodermic needle puncture.
6. Aspirate prior to injection to confirm that the needle is not in a vein or artery.
7. Inject the medication.
8. Keeping your hands behind the needle, grasp the guard with free hand and slide forward toward needle until it is completely covered and guard clicks into place. If audible click is not heard, guard may not be completely activated (see [Figure 1: A and B](#)).
9. Place entire prefilled glass syringe with guard activated into an approved sharps container for proper disposal (see [Figure 1: C](#)).

**Figure 1 – Proper Use of Syringe and UltraSafe® Needle Guard**



### **OVERDOSAGE**

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.

## **ACTION AND CLINICAL PHARMACOLOGY**

### **Mechanism of Action**

HyperHEP B® provides passive immunization for individuals exposed to the hepatitis B virus (HBV) as evidenced by a reduction in the attack rate of hepatitis B following its use (4,14-18).

Cases of type B hepatitis are rarely seen following exposure to HBV in persons with preexisting anti-HBs. No confirmed instance of transmission of hepatitis B has been associated with this product.

### **Pharmacodynamics**

See [ACTION AND CLINICAL PHARMACOLOGY: Mechanism of Action](#).

### **Pharmacokinetics**

In a clinical study in healthy human adults receiving another hyperimmune immune globulin product treated with solvent/detergent, Rabies Immune Globulin (Human), prepared by the same manufacturing process, detectable passive antibody titers were observed in the serum of all subjects by 24 hours post injection and persisted through the 21 day study period. These results suggest that passive immunization with immune globulin products is not affected by the solvent/detergent treatment.

### **Duration of Effect**

The administration of the usual recommended dose of this immune globulin generally results in a detectable level of circulating anti-HBs which persists for approximately 2 months or longer. [Table 5](#) presents the highest antibody (IgG) serum levels were seen in subjects studied (19).

**Table 5 – Antibody (IgG) Serum Levels**

<b>Day</b>	<b>% of Subjects</b>
3	38.9%
7	41.7%
14	11.1%
21	8.3%

Mean values for half-life were between 17.5 and 25 days, with the shortest being 5.9 days and the longest 35 days (19).

## **STORAGE AND STABILITY**

Store at 2-8°C (36-46°F). Do not freeze. Do not use after expiration date. The vials are single use. Once entered, discard any unused contents.

## **DOSAGE FORMS, COMPOSITION AND PACKAGING**

Each vial contains HBs antibody equivalent to or exceeding the potency of anti-HBs (i.e.  $\geq 220$  IU/mL) in a U.S. reference hepatitis B immune globulin (Center for Biologics Evaluation and Research, FDA). The U.S. reference has been tested against the World Health Organization standard Hepatitis B Immune Globulin and found to be equal to 220 international units (IU) per mL.

HyperHEP B® S/D is supplied in a 0.5 mL neonatal single dose disposable syringe with attached needle, a 1 mL single dose disposable syringe with attached needle and a 5 mL single use vial.

## **PART II: SCIENTIFIC INFORMATION**

### **PHARMACEUTICAL INFORMATION**

#### **Drug Substance**

<b>Proper name:</b>	HyperHEP B® S/D
<b>Common name:</b>	Hepatitis B Immune Globulin (Human)

#### **Product Characteristics**

HyperHEP B® S/D treated with solvent/detergent is a sterile solution of hepatitis B hyperimmune immune globulin for intramuscular administration; it contains no preservative.

#### **Viral Inactivation**

The removal and inactivation of spiked model enveloped and non-enveloped viruses during the manufacturing process for HyperHEP B® S/D has been validated in laboratory studies. Human Immunodeficiency Virus, Type 1 (HIV-1), was chosen as the relevant virus for blood products; Bovine Viral Diarrhea Virus (BVDV) was chosen to model Hepatitis C Virus; Pseudorabies Virus (PRV) was chosen to model Hepatitis B Virus and the Herpes viruses; and Reo virus type 3 (Reo) was chosen to model non-enveloped viruses and for its resistance to physical and chemical inactivation.

Significant removal of model enveloped and non-enveloped viruses is seen in the Fraction II+IIIW to Effluent III step and significant removal of PRV and Reo virus is seen in the Effluent III to Filtrate III step. Significant inactivation of enveloped viruses is achieved at the time of treatment of solubilized Cohn Fraction II with solvent/detergent.

### **CLINICAL TRIALS**

Though formal safety and efficacy trials have not been conducted with HyperHEP B® S/D, the clinical effectiveness of Hepatitis B Immune Globulin (Human) in a number of clinical situations is well established. Please refer to the most recent edition of the Canadian Immunization Guide for information regarding efficacy and safety in various indications.

## DETAILED PHARMACOLOGY

### Animal Pharmacology

The effect of solvent-detergent treatment on the pharmacokinetic properties of human immune globulin was studied in rabbits and rhesus monkeys. No significant differences were observed between products with or without solvent-detergent treatment with respect to time to maximal plasma concentration ( $t_{max}$ ), maximum plasma concentration ( $C_{max}$ ), half-life ( $t_{1/2}$ ) and area under the plasma concentration curve (AUC).

### Human Pharmacology

See Product Monograph PART I: [ACTION AND CLINICAL PHARMACOLOGY](#).

## TOXICOLOGY

### Acute Toxicity

Acute and subacute toxicity of solvent/detergent-treated human immune globulin was assessed in rats and rabbits. The intramuscular  $LD_{50}$  of the solvent-detergent treated product for rats and rabbits was  $>2.4$  mL (396 mg/kg). These values indicate a large margin of safety when compared to the clinical dose of 0.133 mL (21.9 mg)/kg.

### Repeated Dose Toxicity

Repeated administration of solvent/detergent-treated human immune globulin to rats and rabbits at dosages approximately nine-fold greater than those administered in the clinic did not produce any clinically relevant toxicity.

### Reproductive Toxicology

Animal reproduction studies have not been conducted with HyperHEP B® S/D.

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## PART III: CONSUMER INFORMATION

### HyperHEP B® S/D

Hepatitis B Immune Globulin (Human)

*Solvent/Detergent Treated*

*This leaflet is Part 3 of a three-part "Product Monograph" published when HyperHEP B® S/D was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about HyperHEP B® S/D. Contact your doctor or pharmacist if you have any questions about the drug.*

#### ABOUT THIS MEDICATION

##### **What the medication is used for:**

HyperHEP B® S/D may be used to prevent you from getting sick if you have been exposed to blood from a hepatitis B-positive patient, sexual contact and newborns infant of mothers with hepatitis B infection.

##### **What it does:**

HyperHEP B® S/D provides antibodies to help prevent or lessen the severity of hepatitis B infections.

##### **When it should not be used:**

You should not use HyperHEP B® S/D if you are allergic to this drug or to any ingredient in the formulation or component of the container.

You should not be given HyperHEP B® S/D if you have any bleeding disorder that would make it unsafe for you to be given an injection into the muscles.

See also SIDE EFFECTS AND WHAT TO DO ABOUT THEM.

##### **What the medicinal ingredient is:**

The medicinal ingredient of HyperHEP B® S/D is human Hepatitis B Immune Globulin (at a concentration of  $\geq 220$  IU/mL).

##### **What the nonmedicinal ingredients are:**

HyperHEP B® S/D also contains the amino acid glycine (at a concentration of 0.21-0.32 M), which acts as a stabilizer.

##### **What dosage forms it comes in:**

HyperHEP B® S/D comes in 0.5 mL (neonatal) and 1mL syringes and 5 mL vials.

#### WARNINGS AND PRECAUTIONS

##### **Serious Warnings and Precautions**

- HyperHEP B® S/D must be injected into muscles only. It should not be injected directly into blood vessels.
- HyperHEP B® S/D like other products made from human plasma, part of our blood, may contain viruses or other agents that can cause infection and illness. However, the processes used to make HyperHEP B® S/D are specifically designed with the ability to destroy or remove these agents if they are present. You should discuss the risks and benefits of this product with your healthcare provider.

BEFORE you use HyperHEP B® S/D talk to your doctor or pharmacist if:

- you are pregnant or breastfeeding
- you have any bleeding disorder
- you have had an allergic reaction to immune globulin or any of the other ingredients in the medicine

#### INTERACTIONS WITH THIS MEDICATION

HyperHEP B® S/D may interfere with some vaccines. However, measles and hepatitis B vaccinations do not interact with HyperHEP B® S/D. Talk with your healthcare professional if you will receive any type of vaccine within 3 months of HyperHEP B® S/D treatment.

See also ABOUT THIS MEDICATION: When it should not be used, and SIDE EFFECTS AND WHAT TO DO ABOUT THEM.

#### PROPER USE OF THIS MEDICATION

##### **Usual dose**

Your doctor will determine the amount of HyperHEP B® S/D that is right for you and when your shots should be given. An intramuscular or IM injection is a shot given into a muscle, usually in the buttocks. A doctor, nurse or other caregiver trained to give injections will give your treatment.

##### **Overdose**

Although there is no information on the effects of HyperHEP B® S/D overdose, experience with similar medicines suggests that the only effect would be pain and tenderness at the needle injection site.

**Missed Dose**

It is important that you receive HyperHEP B® S/D as instructed by your healthcare professional. If your doctor tells you that more than one treatment is required, you should consult him/her if a treatment appointment is missed.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Pain may occur where the injection is given. Talk with your doctor if the pain is severe.

You should talk with your healthcare professional if you experience rash or hives (swelling, redness, intense itching, and burning)., or if you develop swelling of the lips, other parts of the parts of the mouth and throat, eyelids, genitals, hands or feet.

Allergic reactions, although rare, have been reported following the injection of human immune globulin preparations. Talk with your doctor immediately if you experience any of these side effects:

- wheezing or trouble breathing
- chest tightness
- severe abdominal cramps
- severe vomiting
- severe diarrhea

*This is not a complete list of side effects. For any unexpected effects while taking HyperHEP B® S/D, contact your doctor or pharmacist.*

**HOW TO STORE IT**

HyperHEP B® S/D should be stored at 2-8°C (36-46°F). It should not be frozen or used past the expiration date.

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone:	866-234-2345
toll-free fax:	866-678-6789
By email:	<a href="mailto:cadrmp@hc-sc.gc.ca">cadrmp@hc-sc.gc.ca</a>
By regular mail:	National AR Centre Marketed Health Products Safety and Effectiveness Information Division Marketed Health Products Directorate Tunney's Pasture, AL 0701C Ottawa ON K1A 0K9

*NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be obtained by contacting Grifols Canada Ltd., at 1-866-482-5226.

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