PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

HyperHEP B®

Hepatitis B Immunoglobulin (Human)

≥ 220 International Units (IU)/mL Solution

Pre-filled Syringes and Vials for Intramuscular Injection

Manufacturer's Standard

Passive Immunizing Agent

ATC Code: J06BB04

Manufactured by:

Grifols Therapeutics LLC
8368 U.S. 70 Bus. Hwy West
Clayton, North Carolina 27520
U.S.A

Imported and Distributed by:

Grifols Canada Ltd.
5060 Spectrum Way, Suite 405
Mississauga, Ontario
L4W 5N5

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September 8, 2021

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

HyperHEP B® (Hepatitis B Immunoglobulin [Human]) is indicated as an adjunct therapy along with hepatitis B vaccine (HepB vaccine) 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 hepatitis B virus surface antigen (HBsAg)
- Perinatal exposure of infants born to HBsAg-positive mothers
- Sexual exposure to, or needle sharing with an HBsAg-positive person
- Household exposure to persons with acute hepatitis B virus (HBV) infection [text]

1.1 Pediatrics

Safety and effectiveness in the pediatric population have not been established, with the exception of neonates and infants up to 12 months of age (see DOSAGE AND ADMINISTRATION).

1.2 Geriatrics

Safety and effectiveness in geriatric population have not been established.

2 CONTRAINDICATIONS

HyperHEP B® (Hepatitis B immunoglobulin [Human]) is contraindicated in:

- patients who are hypersensitive to the immunoglobulin or to any ingredient in the formulation or component of the container. For a complete listing, see DOSAGE FORMS, COMPOSITION AND PACKAGING.
- HyperHEP B® should not be administered to patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections.
- IgA deficient patients with antibodies against IgA and a history of hypersensitivity.

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions

- The physician should discuss the risks and benefits of this product with the patient, before prescribing or administering to the patient (see WARNINGS AND PRECAUTIONS: General).
- For intramuscular injection only. Do not give intravenously (see WARNINGS AND

PRECAUTIONS: General and see DOSAGE AND ADMINISTRATION).

- Products made from human plasma may contain infectious agents such as viruses that can cause disease (see WARNINGS AND PRECAUTIONS: General)

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

For intramuscular injection only.

Do not give intravenously.

Hepatitis B Immunoglobulin (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.

4.2 Recommended Dose and Dosage Adjustment

Acute Exposure to Blood Containing HBsAg

Table 1 summarizes prophylaxis for percutaneous (needle-stick 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 Immunoglobulin (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 Immunoglobulin (Human) is more effective if combined with a hepatitis B vaccine regimen given immediately but at a different site. Consult hepatitis B vaccine package insert for dosage information regarding that product. There is no established dosage for children.

Table 1 – Course of Action Following Percutaneous ("Needlestick") or Mucosal Exposure to Hepatitis B Virus

Exposed Person		**Source[a]**		
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[b,c,d]	HBIG[b,c,d]	no action necessary[d]
	level unknown and unable to be determined within 48 hours	HBIG[c] + single booster of vaccine	single booster of vaccine ± HBIG[c]	no action necessary
Un-vaccinated	≥10 IU/L	no action necessary	no action necessary	no action necessary
	level unknown at 48 hours or <10 IU/L	HBIG[c] + full vaccine course	full vaccine course ± HBIG[c]	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 Immunoglobulin (Human)
c) Hepatitis B Immunoglobulin (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 Immunoglobulin (Human) in infants at risk depends on administering Hepatitis B Immunoglobulin (Human) on the day of birth. It is therefore vital that HBsAg-positive mothers be identified before delivery.

Hepatitis B Immunoglobulin (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 Immunoglobulin (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 Immunoglobulin (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 Immunoglobulin (Human) should be repeated at 3 months. If hepatitis B vaccine is refused, the 0.5 mL dose of Hepatitis B Immunoglobulin (Human) should be repeated at 3 and 6 months. Hepatitis B Immunoglobulin (Human) administered at birth should not interfere with oral polio and diphtheria-tetanus-pertussis vaccines administered at 2 months of age.

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 Immunoglobulin (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 2 below). Administering the vaccine with Hepatitis B Immunoglobulin (Human) may improve the efficacy of post-

exposure treatment. The vaccine has the added advantage of conferring long-lasting protection.

Table 2 –
Recommendations for Post-exposure Prophylaxis for Sexual Exposure to Hepatitis B

HBIG[a]		Vaccine	
Dose	**Recommended timing**	**Dose**	**Recommended timing**
0.06 mL/kg IM[b]	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[a] treatment[c]

a) HBIG - Hepatitis B Immunoglobulin (Human)
b) Hepatitis B Immunoglobulin (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 Immunoglobulin (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.

4.4 Administration

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. They should not be used if particulate matter and/or discoloration are present. Do not use after expiration date. The pre-filled syringes and vials are single use. Once entered, discard any unused contents immediately into biohazardous waste.

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.

HyperHEP B® is supplied in vials or as pre-filled syringes comprised of a syringe barrel with

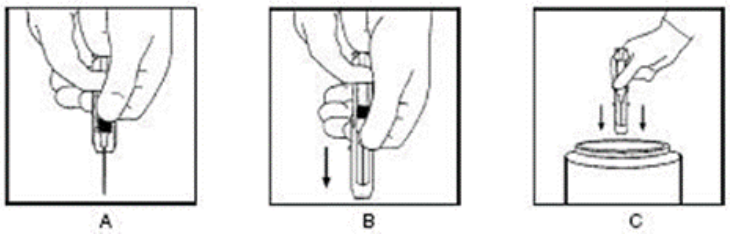
plunger, a needle with a needle cap (shield), and a plastic UltraSafe® needle guard. Please follow instructions below for proper use of pre-filled syringe and UltraSafe® Needle Guard.

Directions for administration of pre-filled syringe:

1. Remove the prefilled syringe from the package. Lift pre-filled syringe by barrel, not by plunger. The plastic UltraSafe® needle guard must be kept in its original position until after administration, and should only be pulled down over the needle for disposal of the used syringe.
2. Twist the plunger rod clockwise until the threads are seated. Do not use if the pre-filled syringe is prematurely engaged.
3. With the rubber needle shield secured on the pre-filled syringe tip, push the plunger rod forward a few millimeters to break any friction seal between the stopper and the glass syringe barrel.
4. Remove the needle shield and expel air bubbles (Do not remove the 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.

Directions for disposal of pre-filled syringe after administration:

1. Keeping your hands away from the needle, grasp the Ultrasafe® needle guard and slide it forward towards the uncovered needle until the plastic guard completely covers the needle and clicks into place. If audible click is not heard, guard may not be completed activated. The needle guard is not meant to be removed from the device, or unlocked after being pulled down. (See Diagrams A and B)
2. Place entire syringe with its Ultrasafe® needle guard activated into an approved sharps container for proper disposal. (See Diagram C)



5 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.

For management of a suspected drug overdose, contact your regional poison control

centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

To help ensure the traceability of biologic products, including biosimilars, health professionals should recognise the importance of recording both the brand name and the non-proprietary (active ingredient) name as well as other product-specific identifiers such as the Drug Identification Number (DIN) and the batch/lot number of the product supplied.

Table 3 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular Injection	Injectable solution; 15-18% protein containing ≥ 220 International Units (IU) per mL	glycine

Description

HyperHEP B® (Hepatitis B Immunoglobulin [Human]) is a clear or slightly opalescent, and colorless or pale yellow or light brown sterile solution of human hepatitis B immunoglobulin for intramuscular administration; it contains no preservative and is supplied in a 0.5 mL neonatal single dose disposable pre-filled syringe with attached needle, a 1 mL single dose disposable pre-filled syringe with attached needle, a 1 mL single use vial, and a 5 mL single use vial.

HyperHEP B® is prepared from pools of human plasma collected from healthy donors by a combination of cold ethanol fractionation caprylate precipitation and filtration, caprylate incubation, anion-exchange chromatography, nanofiltration and low pH incubation. HyperHEP B® consists of 15-18% protein solution at a pH of 4.1 – 4.8 in 0.16 – 0.26 M glycine. The product contains antibody to anti-HBs equivalent to or exceeding the potency of anti-HBs in a U.S. reference hepatitis B immunoglobulin (Center for Biologics Evaluation and Research, FDA). The U.S. reference has been tested against the World Health Organization standard Hepatitis B Immunoglobulin and found to be equal to 220 international units (IU) per mL.

7 WARNINGS AND PRECAUTIONS

Please see the Serious Warnings and Precautions Box at the beginning of Part I: Health Professional Information.

General

HyperHEP B® (Hepatitis B Immunoglobulin [Human]) is made from human plasma and may carry a risk of transmitting infectious agents, e.g. such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite

steps designed to reduce this risk. HyperHEP B® is purified from human plasma obtained from healthy donors. When medicinal biological products are administered, infectious diseases due to transmission of pathogens cannot be totally excluded. However, in the case of products prepared from human plasma, the risk of transmission of pathogens is reduced by: (1) epidemiological controls on the donor population and selection of individual donors by a medical interview; (2) screening of individual donations and plasma pools for viral infection markers; and (3) manufacturing procedures with demonstrated capacity to inactivate/remove pathogens.

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.

Hematologic

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, HyperHEP B® should be given only if the expected benefits outweigh the risks.

Hypersensitivity Reactions

HyperHEP B® should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. Although systemic reactions to intramuscular immunoglobulin preparations are rare, epinephrine should be available for treatment of acute anaphylactic reactions.

Systemic Reactions

Inject intramuscularly only. HyperHEP B® should not be administered intravenously because of the potential for serious reactions (e.g. Renal Dysfunction/Failure, Hemolysis, Transfusion-Related Acute Lung Injury [TRALI]). Do not inject into a blood vessel.

7.1 Special Populations

7.1.1 Pregnant Women

There are no data with HyperHEP B® use in pregnant women to inform a drug-associated risk. Animal reproduction studies have not been conducted with HyperHEP B®. It is also not known whether HyperHEP B® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. HyperHEP B® should be given to a pregnant woman only if clearly needed.

7.1.2 Breast-feeding

There is no information regarding the presence of HyperHEP B® in human milk, the effect on the breastfed infant, or the effects on milk production. The developmental and health benefits

of breastfeeding should be considered along with the mother's clinical need for HyperHEP B® and any potential adverse effects on the breastfed infant from HyperHEP B® or from the underlying maternal condition.

7.1.3 Pediatrics

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

7.1.4 Geriatrics

Safety and effectiveness in geriatric population have not been established.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Local pain and tenderness at the injection site, urticaria and angioedema may occur. In the course of routine injections of large numbers of persons with immunoglobulin there have been a few isolated occurrences of angioneurotic edema, nephrotic syndrome, and anaphylactic shock after injection

8.5 Post-Market Adverse Reactions

The following adverse reactions have been identified during post-approval use with HyperHEP B® (Hepatitis B Immunoglobulin [Human]) made using the previous manufacturing process, (HyperHEP B® S/D). Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Anaphylactic reactions, although rare, have been reported following the injection of human immunoglobulin preparations.

The following have been identified as the most frequently reported post-marketing adverse reactions.

General disorders and administration site conditions:	Injection site reaction*, fatigue, pyrexia
Immune system disorders	Anaphylactic reaction**, hypersensitivity**
Nervous system disorders	Headache
Gastrointestinal disorders	Nausea

* These reactions have been manifested by pain, inflammation, and hemorrhage

** These reactions have been manifested by rash, flushing, angioedema, urticaria and dyspnea

9 DRUG INTERACTIONS

9.4 Drug-Drug Interactions

Table 4 - Established or Potential Drug-Drug Interactions

Name	Source of Evidence	Effect	Clinical comment
Live viral vaccines	CT/T	Although administration of Hepatitis B Immunoglobulin (Human) did not interfere with measles vaccination it is not known whether Hepatitis B Immunoglobulin (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® administration.

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

Hepatitis B vaccine may be administered at the same time as HyperHEP B®, but at a different injection site, without interfering with the immune response.

No interactions with other products are known.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

The anti-HBs antibody in HyperHEP B® (Hepatitis B Immunoglobulin [Human]) is a passive immunizing agent to neutralize hepatitis B virus to prevent disease.

10.2 Pharmacodynamics

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.

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

10.3 Pharmacokinetics

In a clinical study of 12 healthy human subjects receiving a 20 IU/kg intramuscular dose of HyperRAB® (Rabies Immunoglobulin [Human]), detectable passive rabies neutralizing antibody was present by the second day and persisted through the 21 day follow-up evaluation period. HyperRAB® is manufactured via the same process, using the same controls as HyperHEP B®, except that the starting material (plasma) has a higher titer of rabies antibody, versus hepatitis B antibody. The figure below shows the mean levels of rabies virus antibodies in IU/mL across the 21 day evaluation period and indicates that the titer remains stable during

this period.

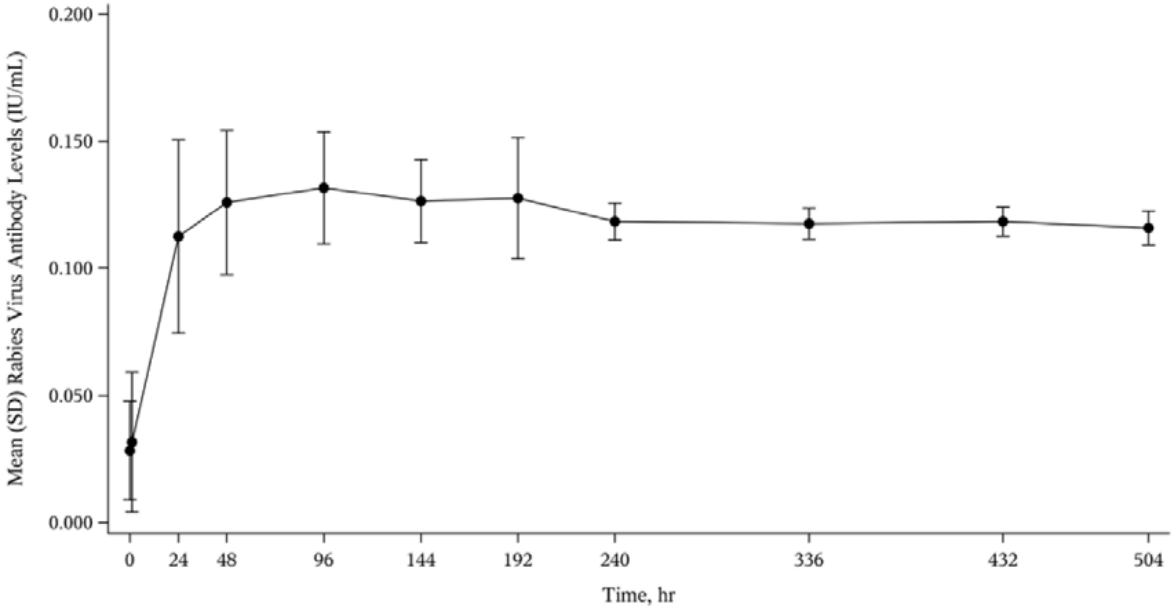


Figure: Mean (Standard Deviation) Rabies Virus Antibody Levels (IU/mL) versus Time following a Single 20 IU/kg Dose of HyperRAB® by Intramuscular Injection

Duration of Effect

The administration of the usual recommended dose of this immunoglobulin 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.

Table 5 – Antibody (IgG) Serum Levels

Day	% of Subjects
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.

11 STORAGE, STABILITY AND DISPOSAL

HyperHEP B® (Hepatitis B Immunoglobulin [Human]) should be stored at 2-8°C. Do not freeze. Do not use after expiration date. The pre-filled syringes and vials are single use. Once entered, discard any unused contents.

12 SPECIAL HANDLING INSTRUCTIONS

Not Applicable.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: HyperHEP B®

Common name: Hepatitis B Immunoglobulin (Human)

Product Characteristics:

HyperHEP B® is a clear or slightly opalescent, and colorless or pale yellow or light brown sterile solution of human hepatitis B immunoglobulin for intramuscular administration. HyperHEP B® contains no preservative. HyperHEP B® is prepared from pools of human plasma collected from healthy donors (hyperimmunized with hepatitis B vaccine) by a combination of cold ethanol fractionation, caprylate precipitation and filtration, caprylate incubation, anion-exchange chromatography, nanofiltration and low pH incubation. HyperHEP B® consists of 15 to 18% protein at pH 4.1 to 4.8 in 0.16 to 0.26 M glycine. The product contains antibody to hepatitis B equivalent to or exceeding the potency of anti-Hepatitis B in a U.S. reference hepatitis B immunoglobulin (U.S. FDA, Center for Biologics Evaluation and Research). The U.S. reference has been tested against the World Health Organization standard Hepatitis B Immunoglobulin and found to be equal to 220 international units (IU) per mL.

Viral Inactivation

When medicinal biological products are administered, infectious diseases due to transmission of pathogens cannot be totally excluded. However, in the case of products prepared from human plasma, the risk of transmission of pathogens is reduced by epidemiological surveillance of the donor population and selection of individual donors by medical interview; testing of individual donations and plasma pools; and the presence in the manufacturing processes of steps with demonstrated capacity to inactivate/remove pathogens.

In the manufacturing process of HyperHEP B®, there are several steps with the capacity for viral inactivation or removal. The main steps of the manufacturing process that contribute to the virus clearance capacity are as follows:

- Caprylate precipitation/depth filtration
- Caprylate incubation
- Depth filtration
- Column chromatography
- Nanofiltration
- Low pH final container incubation

To provide additional assurance of the pathogen safety of the final product, the capacity of the HyperHEP B® manufacturing process to remove and/or inactivate viruses has been demonstrated by laboratory spiking studies on a scaled down process model using a wide range of viruses with diverse physicochemical properties.

The combination of all of the above mentioned measures provides the final product with a high margin of safety from the potential risk of transmission of infectious viruses.

The caprylate/chromatography manufacturing process was also investigated for its capacity to decrease the infectivity of an experimental agent of transmissible spongiform encephalopathy (TSE), considered as a model for the variant Creutzfeldt-Jakob disease (vCJD), and Creutzfeldt-Jakob disease (CJD) agents. These studies provide reasonable assurance that low levels of vCJD/CJD agent infectivity, if present in the starting material, would be removed by the caprylate/chromatography manufacturing process.

14 CLINICAL TRIALS

Though formal safety and efficacy trials have not been conducted with HyperHEP B®, the clinical effectiveness of Hepatitis B Immunoglobulin (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.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

Not Applicable.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

HyperHEP B®

Hepatitis B Immunoglobulin (Human)

Read this carefully before you start taking **HyperHEP B®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **HyperHEP B®**.

Serious Warnings and Precautions

- Your doctor should discuss the risks and benefits of this product with you before prescribing or administering it to you.
- HyperHEP B® must be injected into muscles only. It should not be injected directly into blood vessels.
- HyperHEP B® 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® are specifically designed with the ability to destroy or remove these agents if they are present.

What is HyperHEP B® used for?

HyperHEP B® may be used to prevent you from getting sick if you have been exposed to blood from a hepatitis B-positive person, or if you have had sexual contact with a hepatitis B-positive person. It may also be used to prevent your newborn baby from getting sick if born to a hepatitis B-positive mother.

How does HyperHEP B® work?

Vaccines work by stimulating your immune system to produce antibodies against a particular disease. Because vaccines require this immune response, they take time to work and are not immediately effective**. HyperHEP B®** is made from the blood of people who have already been vaccinated against hepatitis B and therefore already contains hepatitis B antibodies. It starts working immediately after being injected and helps to protect you from getting hepatitis B until your body starts producing its own antibodies in response to the vaccine.

What are the ingredients in HyperHEP B®?

Medicinal ingredient: Human Hepatitis B Immunoglobulin
Non-medicinal ingredient: Glycine

HyperHEP B® comes in the following dosage forms:

Single use syringes and vials at a concentration of ≥ 220 IU/mL

- 0.5 mL (neonatal) pre-filled syringe
- 1 mL pre-filled syringe
- 1 mL vial
- 5 mL vial

Do not use HyperHEP B® if:

- you are allergic to this drug or to any ingredient in the formulation or component of the container.
- you have any bleeding disorder that would make it unsafe for you to be given an injection into the muscles.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take HyperHEP B®. Talk about any health conditions or problems you may have, including if you:

- are pregnant or breastfeeding
- have been diagnosed with thrombocytopenia or any other bleeding disorder
- have previously had an allergic reaction to immunoglobulin or any of the other ingredients in the medicine

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with HyperHEP B®:

Certain types of vaccines.
However, measles and hepatitis B vaccinations do not interact with **HyperHEP B®**. Talk with your healthcare professional if you will receive any type of vaccine within 3 months of **HyperHEP B®** treatment.

How to take HyperHEP B®:

An intramuscular or IM injection is a shot given into a muscle, usually in the thigh or shoulder. A doctor, nurse or other caregiver trained to give injections will give your treatment.

Usual dose:

Your doctor will determine the amount of **HyperHEP B®** that is right for you and when your shots should be given.

Overdose:

Although there is no information on the effects of **HyperHEP B®** 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®** 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.

What are possible side effects from using HyperHEP B®?

These are not all the possible side effects you may have when taking **HyperHEP B®**. If you experience any side effects not listed here, tell your healthcare professional.

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 immunoglobulin preparations. Talk with your doctor immediately if you experience any of these side effects, which may be symptoms of an allergic reaction: wheezing or trouble breathing, chest tightness, severe abdominal cramps, severe vomiting, or severe diarrhea.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

HyperHEP B® should be stored at 2-8°C. It should not be frozen or used past the expiration date.

Keep out of reach and sight of children.

If you want more information about HyperHEP B®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; or by calling 1-866-482-5226.

This leaflet was prepared by Grifols Therapeutics LLC.

Last Revised: September 8, 2021