

HyperHEP B

Hepatitis B Immunoglobulin (Human)

220 IU/mL, Solution for Intramuscular Injection

What is in this leaflet

Please read this leaflet carefully before you start using HyperHEP B.

This leaflet answers some common questions about HyperHEP B. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using HyperHEP B against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with you. You may need to read it again.

What HyperHEP B is used for

HyperHEP B may prevent you from becoming infected with the hepatitis b virus which causes a serious liver disease, type B hepatitis. HyperHEP B contains proteins called antibodies that will neutralize hepatitis B virus. This medicine provides you with immediate, temporary protection to hepatitis B virus infection.

You will only need HyperHEP B if one of the following statements is true:

- you never received the hepatitis B vaccine series
- you never completed all of the required hepatitis B vaccine booster shots
- your body did not build its own antibodies to hepatitis B virus from those vaccine shots
- your antibody level has since dropped off

Cases of type B hepatitis rarely occur following exposure to hepatitis B virus in persons with pre-existing antibodies.

Your doctor will likely give you hepatitis B vaccine at the same time you get HyperHEP B treatment. HyperHEP B protects you with its antibodies while your body builds its own longer-lasting antibodies as a result of vaccination. HyperHEP B does not interfere with your body's ability to make its own antibody to the virus. Your doctor will discuss with you when to come back for additional vaccine boosters.

HyperHEP B treatment is useful in the following situations:

- HyperHEP B may protect you from infection when you have had close contact with blood or body fluids infected with hepatitis B virus. Some examples are s:
 - An accidental stick with a hypodermic needle contaminated with infected blood.
 - A splash of infected blood or body fluid into your eye.
 - A laboratory worker who ingests infected blood or body fluid when using a mouth pipetting technique.

Your doctor should give you HyperHEP B within 1 week of contact with infected blood or body fluid. Your doctor will also administer hepatitis B vaccine and may schedule you for future vaccine boosters which must be followed to prevent you from becoming infected.

- HyperHEP B may protect your newly born baby from getting infected with hepatitis B virus during birthing when you are its mother and are already infected. Your doctor will give your baby HyperHEP B shortly after birth. Your doctor will also administer hepatitis B vaccine and schedule your baby for future boosters which must be followed to prevent your baby from becoming infected.
- HyperHEP B may protect you from infection with hepatitis B virus if you have had sexual activity with a partner who is infected with hepatitis B virus. Your doctor should give you HyperHEP B within 2 weeks of sexual activity with your infected partner or if sexual activity will continue with your partner. Your doctor will also administer hepatitis B vaccine and may schedule future boosters for you which must be followed to prevent you from becoming infected.
- HyperHEP B may protect your infant of less than 1 year of age from getting hepatitis B when you or its main caregiver is infected with hepatitis B virus. Your doctor will also administer hepatitis B vaccine and may schedule future boosters for your baby which must be followed to prevent your baby from becoming infected.
- HyperHEP B may protect you from becoming infected if another person in your household has type B hepatitis and you are not immune to the virus. Your doctor will also administer hepatitis B vaccine and may schedule future boosters for you which must be followed to prevent you from becoming infected.
- HyperHEP B may protect you from getting type B hepatitis if you are unable to develop immune protection and you are receiving haemodialysis.

- HyperHEP B may protect you from getting type B hepatitis if you are taking certain other medicines made from human blood.

Your doctor may have prescribed HyperHEP B for another reason.

This medicine belongs to the medicine's group called immune sera and immunoglobulins (antibodies). It is made from human blood. No confirmed instance of transmission of hepatitis B virus has been associated with this product.

Ask your doctor if you have any questions about why HyperHEP B has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine or other medicines made from human blood antibodies are habit-forming.

Before you use HyperHEP B

When you must not use it

Do not use HyperHEP B if:

- you know you cannot tolerate medicines made with human immunoglobulin, especially if you have such a history, or if you know you are immunoglobulin A (IgA) deficient.
- you suffer from severe low blood platelets (thrombocytopenia) or from a blood clotting disorder.

If you are not sure whether you should use HyperHEP B, talk to your doctor.

Before you start to use it

Tell your doctor if:

- you are pregnant or intend to become pregnant. It is not known whether HyperHEP B is harmful to an unborn baby when given to a pregnant woman. From clinical experience with other human immunoglobulin medicines, harmful effects from HyperHEP B are not expected on the course of pregnancy, on your foetus and on your newborn child. Your doctor will give you HyperHEP B only if it is clearly needed.
- you are breastfeeding. Immunoglobulins are excreted into the milk and may contribute to the transfer of protective antibodies to your baby.

- you do not tolerate medicines made from blood, including human immunoglobulins.
- you are concerned that your child may be treated with HyperHEP B. The safety and effectiveness of HyperHEP B in children have not been established.

If you have not told your doctor about any of the above, tell your doctor before you or your infant is treated with HyperHEP B.

Your doctor must not inject HyperHEP B into a blood vessel (intravenously) because of the possibility for serious reactions. Injections should be into a muscle (intramuscularly) and given with care in order to be certain that the needle is not in a blood vessel. Your doctor should observe you or your infant for at least 20 minutes afterward.

Your doctor will give you the HyperHEP B injection into a large muscle in the upper arm or outer thigh, but not into the muscles of the buttocks which could damage the major leg nerve. Your child should get the HyperHEP B injection only into the outer thigh muscle. Talk to your doctor about which muscles to use since your situation may be different.

There is a possibility that your body could react to HyperHEP B. Allergic reactions to Hepatitis B Immunoglobulin (Human) are rare when the medicine is given intramuscularly. If you go into shock, your doctor will treat you by following standard guidelines for shock therapy. Your body may not tolerate HyperHEP B if you have the very rare condition of “IgA deficiency” and your body has already made its own antibodies against immunoglobulin A (IgA). If your doctor suspects that you are experiencing an allergic or anaphylactic reaction during administration of HyperHEP B, your doctor must immediately discontinue the injection.

Special safety warning

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections from viruses or the Creutzfeldt-Jakob Disease (CJD) agent from being passed on to patients. These include careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded, and the testing of each donation and pools of plasma for signs of virus or virus infections. Manufacturers of these products also include steps in the processing of the blood or plasma that can inactivate or remove viruses. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This applies to any unknown or emerging viruses or other types of infections.

Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some viral infections, particularly type C hepatitis (hepatitis C). All infections, thought by a physician, to possibly have been transmitted by this medicine should be reported by the physician or other healthcare provider to Medica Limited (Phone (09) 526-1944)).

Your doctor should discuss the risks and benefits of this medicine with you before administering it to you.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking HyperHEP B.

Some medicines may interfere with HyperHEP B. These include:

- live virus vaccines, such as measles, rubella (German measles), mumps and varicella (chickenpox) which are usually given together. Hepatitis B Immunoglobulin (Human) does not interfere with measles vaccine, but it is not known whether HyperHEP B may impair your body's ability to build immunity to rubella, mumps or varicella. Therefore, delay getting these vaccines until approximately 3 months after your last HyperHEP B treatment.
- hepatitis B vaccine, but only if your doctor injects it into the very same muscle as HyperHEP B. HyperHEP B and hepatitis B vaccine may be administered at the same time, but at different injection sites. Hepatitis B Immunoglobulin (Human) at the recommended dose does not interfere with the immune response to hepatitis B vaccine.

These medicines may be affected by HyperHEP B, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking HyperHEP B. Interactions with other medicines are not known.

How to use HyperHEP B

How much to take

Your doctor will calculate how much HyperHEP B you receive based on your weight. A standard dose is 0.06 millilitres of HyperHEP B for every 1 kilogram of body weight. A standard dose for an infant less than 1 year of age is 0.5 millilitres. Your doctor will inject you with HyperHEP B into the large muscle of the upper arm or outer thigh.

When you contact blood or body fluid which is possibly infected with hepatitis B virus

Your doctor will decide on the proper treatment for you based upon the likeliness that the blood or body fluid is infected with hepatitis B virus and whether you are immune

to hepatitis B virus. Your doctor may decide to test your blood for immunity (antibodies) to hepatitis B virus. If you are already immune, the test will show that you have at least 100 units of antibody for each 1 millilitre of blood. Then you may only receive a hepatitis B vaccine booster shot.

When your doctor is certain that you have contacted infected blood or body fluid and you are not immune to the virus, your doctor may give you a standard dose of 0.06 millilitres per kilogram of HyperHEP B (about 6 millilitres for a 100 kilogram person). HyperHEP B will likely protect you if you receive it within 7 days of your first exposure to the infected blood or body fluid. You should get a hepatitis B vaccine shot, too. Your doctor should not inject the same muscle with both HyperHEP B and hepatitis B vaccine, but should inject the vaccine on the opposite side. If you know you are allergic to the hepatitis B vaccine or if you refuse the vaccine, your doctor may give you another injection of HyperHEP B in 1 month.

If you have had the full series of hepatitis B vaccination and booster shots, your doctor may decide not to test you for antibodies, especially if the blood or body fluid is not likely or not certain to be infected with hepatitis B virus. You probably will not get HyperHEP B. Your doctor may administer only hepatitis B vaccine, or may prescribe nothing.

Your doctor may want you to return for additional hepatitis B vaccine boosters after 1 month and again after 6 months. You must have all three shots to develop protection, or you could become sick with hepatitis. You should get all of your hepatitis B vaccine shots in the muscle of the upper arm or outer thigh.

When you are infected with hepatitis B virus and are giving birth

Your doctor will decide on the proper treatment for your newborn baby based upon the likeliness that you, the mother, are infected with hepatitis B virus. If testing shows you have the virus, your doctor will give your baby an injection of 0.5 millilitres of HyperHEP B into the outer thigh muscle. Your doctor should give this shot within 12 hours of delivery, but no later than 48 hours or HyperHEP B may not be effective. Your doctor will also inject your baby with hepatitis B vaccine into the opposite thigh muscle.

If your doctor delays giving the vaccine for more than 3 months from birth because of the medical condition of your baby, your doctor may give a second injection of HyperHEP B at 3 months of age.

If you refuse to have your baby vaccinated with the hepatitis B vaccine, your doctor may give a second injection of HyperHEP B at 3 months and a third injection at 6 months.

When you have sex with a person who is infected with hepatitis B virus

Your doctor may treat you with HyperHEP B if you had sexual activity with a partner who is infected with hepatitis B virus and if you have not been vaccinated against hepatitis B virus. In this case your doctor may give you a standard dose of 0.06 millilitres per kilogram of HyperHEP B (about 6 millilitres for a 100 kilogram person). Your doctor may also prescribe HyperHEP B if you plan on continuing sexual relations with this infected partner.

Your doctor will also give you a hepatitis B vaccine shot. Your doctor should not inject the same muscle with both HyperHEP B and hepatitis B vaccine. Your doctor may want you to return for additional hepatitis B vaccine booster shots; otherwise you could become infected with hepatitis B virus.

When a person in your household is infected with hepatitis B virus

If you are infected with hepatitis B virus and are the mother or primary caregiver to a baby of less than 1 year of age, the doctor may give the baby a standard infant dose of HyperHEP B of 0.5 millilitres in the outer thigh muscle. Your baby will also receive hepatitis B vaccine, but in the opposite thigh.

If another person in the household is infected with hepatitis B virus, your doctor may treat you with HyperHEP B if you came in contact with their blood or body fluids and if you have no immunity (antibodies) of your own to the virus. An example of household contact is sharing a toothbrush or a razor. Your doctor should give you HyperHEP B within 14 days of this kind of exposure to the virus. Your doctor will also give you hepatitis B vaccine.

Some people who are infected with hepatitis B virus never rid the virus from their body. They are called chronic carriers and they have the virus in their bloodstream for life. Your doctor will give hepatitis B vaccine to anyone in your household who has not been vaccinated when another member of the household is a chronic hepatitis B virus carrier.

When you are on haemodialysis

Your doctor may treat you with HyperHEP B if you are receiving regular renal haemodialysis and you are not able to make enough of your own antibodies to neutralize hepatitis B virus after receiving the vaccine. Please consult your doctor for additional information.

When you are taking certain other medications made from human blood

Your doctor may treat you with HyperHEP B if you are receiving certain medicines made from human blood. Please consult your doctor for additional information.

When to take it

Your doctor should treat you with HyperHEP B within 1 week of your contact with infected blood or body fluids or within 2 weeks of your sexual activity with an infected partner. Hepatitis B vaccine must also be given.

Your doctor should treat your newborn baby with HyperHEP B within 12 hours of delivery when you, the mother, are infected with the hepatitis B virus. The latest your doctor should treat your baby is 48 hours after delivery. Your baby must also receive hepatitis B vaccine.

Your doctor should treat you with HyperHEP B within 2 weeks of your household contact with blood or body fluid from an infected member of your home. You must also receive hepatitis B vaccine.

How long to take it

If you can not or will not take the hepatitis B vaccine, your doctor may require you to return over the next 1 to 6 months for one or more additional treatments with HyperHEP B.

If you forget to take it

If your doctor requires you to take one or more additional injections of HyperHEP B and you miss your dose, please consult with your doctor for instructions.

While you are using HyperHEP B

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking HyperHEP B.

Things you must not do

Do not give HyperHEP B to anyone else, even if they have the same condition as you.

Things to be careful of

No effects on ability to drive and use machines have been observed.

If you are having a blood test after receiving HyperHEP B, please inform the analyst or your doctor that you have taken this medicine. The level of certain antibodies can rise which may result in misreading positive results in serological testing.

In case of overdose

If you take too much (overdose)

Clinical experience with other immunoglobulin preparations suggests that the only symptoms of overdose would be pain and tenderness at the injection site.

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much HyperHEP B.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after being treated with HyperHEP B.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if any of the following side effects happen during or after the injection:

- Pain and tenderness at the injection site.
- Hives (urticaria) and welts (angioedema)

Your doctor can prevent these side effects by dividing your dose over several injection sites.

Occasionally, you may experience:

- Fever
- Cutaneous reactions such as an itchy red rash
- Chills

Rarely, you may experience:

- Vomiting
- Nausea
- Low blood pressure (hypotension)
- Rapid heartbeat (tachycardia)
- Allergic or anaphylactic type reactions including shock

When medicinal products prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This applies to any unknown or emerging viruses or other types of infections.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other side effects or if any of the above side effects gets serious.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using HyperHEP B

Storage

Your doctor or pharmacist must store HyperHEP B in a refrigerator (2°C to 8°C), never in a freezer. Your doctor must never use HyperHEP B after the expiry date stamped on the label.

Your doctor must never use HyperHEP B that was ever frozen, is cloudy or has particles in it.

All medicines, including HyperHEP B, must be stored out of reach of children.

Disposal

Your doctor will dispose of any unused or expired medicine or medical waste in accordance with local requirements.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

HyperHEP B is a colourless to pale yellow or pink liquid. It is supplied in a syringe with an attached UltraSafe® Needle Guard. It is also available in a glass vial.

- 0.5 mL neonatal single dose syringe with attached needle and needle guard
- 1.0 mL single dose syringe with attached needle and needle guard
- 5.0 mL single dose vial

Ingredients

Active ingredient:

- 220 International Units per millilitre (IU/mL) of Hepatitis B Immunoglobulin (Human), USP

Inactive ingredients:

- Glycine, USP

HyperHEP B is sterile and does not contain a preservative. The medicine, syringes, needles, vials and packaging materials do not contain latex.

Sponsor Details

HyperHEP B is supplied in New Zealand by:

Medica Limited

3 Te Kea Place,
Albany, Auckland 0632
NEW ZEALAND

Phone (09) 526-1944

Date of Preparation

This leaflet was prepared on 1 December 2011.