



Package leaflet: Information for the user



Hepatect® CP 50 IU/ml solution for infusion

Human hepatitis B immunoglobulin for intravenous administration

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Hepatect CP is and what it is used for
2. What you need to know before you use Hepatect CP
3. How to use Hepatect CP
4. Possible side-effects
5. How to store Hepatect CP
6. Contents of the pack and other information

1. What Hepatect CP is and what it is used for

Hepatect CP contains the active ingredient human hepatitis B immunoglobulin, which can protect you from hepatitis B. Hepatitis B is an inflammation of the liver caused by the hepatitis B virus. Hepatect CP is a solution for infusion (into a vein) and comes in vials containing 2 ml (100 International Units [IU]), 10 ml (500 IU), 40 ml (2000 IU) and 100 ml (5000 IU).

Hepatect CP is used to give immediate and long-term immunity (protection) to:

- prevent hepatitis B infection in patients who have not been vaccinated or fully vaccinated against hepatitis B and who are at risk of infection with hepatitis B.
- prevent infection of a transplanted liver in patients who test positive for hepatitis B.
- newborn babies whose mothers are infected with the hepatitis B virus.
- protect patients for whom hepatitis B vaccination has not provided adequate protection.

2. What you need to know before you use Hepatect CP

Do not use Hepatect CP:

- if you are allergic to human immunoglobulin or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- if you have already been fully vaccinated against hepatitis B and you are immune.

Warning and precautions

Talk to your doctor, pharmacist or nurse before using Hepatect CP

- if you suffer from a condition with low antibody levels in your blood (hypo- or agammaglobulinemia)
- if you have had a reaction to other antibodies (in rare cases you may be at risk of allergic reactions)

Your doctor will take special care if you are overweight, elderly, diabetic, or if you suffer from high blood pressure, low blood volume (hypovolaemia), have an IgA deficiency, have problems with your blood vessels (vascular diseases) or are at risk for thrombotic events.

Inform your doctor if you have been vaccinated against hepatitis B within the past four weeks. You may need to be re-vaccinated if you are given Hepatect CP.

Please note - reactions

You will be carefully observed during the infusion period with Hepatect CP to make sure that you do not suffer a reaction. Your doctor will make sure that the rate at which Hepatect CP is infused is suitable for you.

If you have a reaction during the infusion of Hepatect CP, tell your doctor immediately. The rate of infusion can be slowed or the infusion can be stopped altogether.

Information on transmission of infectious agents

Hepatect CP is made from human plasma (the liquid part of blood). When medicines are made from human blood or plasma, certain measures are put in place to prevent infections 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,
- the testing of each donation and pools of plasma for signs of virus/infections,
- the inclusion of 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 also applies to any unknown or emerging viruses or other types of infections.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus.

The measures taken may be of limited value against non-enveloped viruses such as hepatitis A virus and parvovirus B19.

Immunoglobulins have not been associated with hepatitis A or parvovirus B19 infections possibly because the antibodies against these infections, which are contained in the product, are protective.

It is strongly recommended that every time you receive a dose of Hepatect CP the name and batch number of the medicine are recorded in order to maintain a record of the batches used.

Other medicines and Hepatect CP

Tell your doctor if you are taking or have recently taken any other medicines.

Hepatect CP can reduce the effectiveness of some vaccines such as:

- measles
- rubella
- mumps
- chicken pox

You may have to wait up to 3 months before you can have some vaccines.

Effects on blood tests

Hepatect CP can affect blood tests. If you have a blood test after receiving Hepatect CP, please inform the person taking your blood or your doctor that you have received Hepatect CP.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Your doctor will decide if Hepatect CP may be used during pregnancy and breast-feeding.

Driving and using machines

The ability to drive and operate machines may be impaired by some adverse reactions associated with Hepatect CP. Patients who experience adverse reactions during treatment should wait for these to resolve before driving or operating machines.

The following information is intended for healthcare professionals only:

Method of administration

Hepatect CP should be infused intravenously at an initial rate of 0.1 ml/kg body weight/hour for 10 minutes. If well tolerated, the rate of administration may gradually be increased to a maximum of 1 ml/kg body weight/hour.

Clinical experience in newborns of hepatitis B virus carrier mothers has shown, that Hepatect CP intravenously used at an infusion rate of 2 ml in-between 5 to 15 minutes has been well tolerated.

Special Precautions

Thromboembolic complications have been associated with the use of normal IVIg. Therefore, caution is recommended especially for patients with thrombotic risk factors.

Patients should be monitored for serum anti-HBs antibody levels regularly.

Certain severe adverse drug reactions may be related to the rate of infusion. The recommended infusion rate given under "Method of administration" must be closely followed. Patients must be closely monitored and carefully observed for any symptoms throughout the infusion period. Any infusion-related adverse events should be treated by lowering the infusion rate or by stopping the infusion.

Hepatect CP contains IgA. Individuals who are deficient in IgA have the potential for developing IgA antibodies and may have anaphylactic reactions after administration of blood components containing IgA. The physician must therefore weigh the benefit of treatment with Hepatect CP against the potential risk of hypersensitivity reactions.

During graft re-infection preventive therapy very rare cases of intolerance reactions may be linked to an interval increase between administrations.

It is strongly recommended that every time Hepatect CP is administered to a patient, the name and batch number of the product is recorded.

Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the injection. In case of shock, standard medical treatment for shock should be implemented.

Incompatibilities

This medicinal product must not be mixed with other medicinal products.

No other preparations may be added to the Hepatect CP solution as any change in the electrolyte concentration or the pH may result in precipitation or denaturation of the proteins.

Instructions for handling and disposal

Do not use Hepatect CP after the expiry date which is stated on the label and outer carton.

The product must be brought to room or body temperature before use.

The solution should be clear or slightly opalescent. Do not use solutions that are cloudy or have deposits.

The product once opened should be used immediately.

Any unused product or waste material should be disposed of in accordance with local requirements.

Dosage

Unless otherwise prescribed, the following recommendations apply:

Prevention of hepatitis B re-infection after liver transplantation for hepatitis B induced liver failure:

In adults:

10 000 IU on the day of transplantation, peri-operatively then 2000-10 000 IU (40-200 ml)/day for 7 days, and as necessary to maintain antibody levels above 100-150 IU/l in HBV-DNA negative patients and above 500 IU/l in HBV-DNA positive patients.

In children:

Posology should be adjusted according to body surface area, on the basis of 10 000 IU/1.73 m².

Immunoprophylaxis of hepatitis B:

- Prevention of hepatitis B in case of accidental exposure in non-immunised subjects:  
At least 500 IU (10 ml), depending on the intensity of exposure, as soon as possible after exposure, and preferably within 24 - 72 hours.

- Immunoprophylaxis of hepatitis B in haemodialysed patients:  
8-12 IU (0.16-0.24 ml)/kg with a maximum of 500 IU (10 ml), every 2 months until seroconversion following vaccination.

- Prevention of hepatitis B in the newborn, of a hepatitis B virus carrier-mother, at birth or as soon as possible after birth:  
30-100 IU (0.6-2 ml)/kg. The hepatitis B immunoglobulin administration may be repeated until seroconversion following vaccination.

In all these situations, vaccination against hepatitis B virus is highly recommended. The first vaccine dose can be injected on the same day as human hepatitis B immunoglobulin, however in different sites.

In subjects who did not show an immune response (no measurable hepatitis B antibodies) after vaccination, and for whom continuous prevention is necessary, administration of 500 IU (10 ml) to adults and 8 IU (0.16 ml)/kg to children every 2 months can be considered; a minimum protective antibody titre is considered to be 10 mIU/mL.

3. How to use Hepatect CP

Hepatect CP is intended for intravenous administration (infusion into a vein). It is given to you by a doctor or nurse. The recommended dose will depend on your condition and your body weight. Your doctor will know the right amount to give you.

At the beginning of your infusion you will receive Hepatect CP at a slow rate. Your doctor may then gradually increase the infusion rate.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can have side effects, although not everybody gets them.

Rarely, the following may occur:

- chills
- headache
- fever
- vomiting
- malaise (feeling sick)
- nausea (urge to vomit)
- low blood pressure
- allergic reactions
- skin (cutaneous) reactions such as erythema (redness), itching
- tachycardia (faster heart beat)

Very rarely, the following may occur:

- severe allergic reactions (anaphylactic shock)
- joint pain

With human immunoglobulin the following has been observed:

- temporary meningitis (inflammation of the brain lining)
- decrease of red blood cells (reversible haemolytic anaemia/haemolysis)
- an increase in the serum creatinine (a waste product) and/or sudden kidney failure
- cases of blood clots in the veins (thromboembolic reactions) have been reported in the elderly, in patients with signs of cerebral or cardiac ischemia, and in overweight and patients with very low blood volume (severely hypovolaemic).

If a side effect occurs, the infusion rate will be decreased or stopped.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: www.hpra.ie  
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hepatect CP

Keep this medicine out of the sight and reach of children.  
Your pharmacist or doctor knows how to store Hepatect CP.  
It should be kept in the outer carton to protect it from light.  
Hepatect CP should be stored in a refrigerator at 2-8 °C. Do not freeze.

6. Contents of the pack and other information

What Hepatect CP contains:

- The active substance of Hepatect CP is human hepatitis B immunoglobulin for intravenous administration.  
Hepatect CP contains 50 mg/ml of human plasma protein of which at least 96 % is immunoglobulin G (IgG). The content of hepatitis B antibody is 50 IU/ml. The maximum immunoglobulin A (IgA) content is 2,000 micrograms/ml. The IgG subclass distribution is approx.  
59 % IgG1, 35 % IgG2, 3 % IgG3 and 3 % IgG4.
- The other ingredients are glycine and water for injections.

What Hepatect CP looks like and the contents of the pack

Hepatect CP is a solution for infusion. The solution is clear to faintly opalescent (milky colours like an opal) and colourless to pale yellow.

Pack containing 1 vial with 100 IU in 2 ml solution  
Pack containing 1 vial with 500 IU in 10 ml solution  
Pack containing 1 vial with 2000 IU in 40 ml solution  
Pack containing 1 vial with 5000 IU in 100 ml solution

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Biotest Pharma GmbH  
Landsteinerstrasse 5  
63303 Dreieich  
Germany  
Tel.: + 49 6103 801-0  
Fax: + 49 6103 801-150

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