B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fovepta 200 IU solution for injection in pre-filled syringe
Human hepatitis B immunoglobulin

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may want to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your newborn. Do not pass it on to others.
- If any of the side effects gets serious in your newborn, or if you notice in your newborn any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT FOVEPTA IS AND WHAT IT IS USED FOR

What Fovepta is

Fovepta contains antibodies against the hepatitis B virus which are the body's own defensive substances to protect your newborn from hepatitis B. Hepatitis B is an inflammation of the liver caused by the hepatitis B virus.

What Fovepta is used for

Fovepta is used to prevent infection of hepatitis B in the newborn of a hepatitis B virus carrier-mother.

2. BEFORE YOU USE FOVEPTA

Please read this section carefully. You and your doctor should carefully consider all items mentioned here before the newborn receives Fovepta.

Fovepta should not be used
- if **your newborn is hypersensitive (allergic) to human immunoglobulin or any of the other ingredients of Fovepta.**

Possible signs of an allergic reaction are sudden wheeziness, difficulty in breathing, fast pulse, swelling of the eyelids, face, lips, throat or tongue, as well as rash or itching.

Take special care with Fovepta

Fovepta is for subcutaneous and intramuscular injection, means under the skin or in the muscle. Injection into a vein or other blood vessel may result in allergic shock.

Please tell your doctor or healthcare professional prior to treatment
- if you have been told that your newborn has antibodies against immunoglobulins of the type IgA in the blood. This is very rare and may result in allergic reactions.

Your newborn may be hypersensitive (allergic) to immunoglobulins (antibodies). Particularly if

your newborn does not have enough immunoglobulins of the type IgA in the blood, allergic reactions such as a sudden fall in blood pressure or shock may occur.

Your newborn will be carefully observed shortly after the injection with Fovepta to make sure that your neworn does not suffer from a reaction. Please tell your doctor or healthcare professional immediately if you notice such reaction in your newborn after the injection of Fovepta.

For the safety of your newborn the antibody levels will be monitored regularly.

Information on the starting material of Fovepta and the possibility of transmission of infectious agents:

The starting material or what Fovepta is made from is human blood plasma (the liquid part of the 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, *and*
- the testing of each donation and pools of plasma for signs of virus/infections.

Manufacturers of these medicines 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 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 (HBV) and hepatitis C virus (HCV), and for the non-enveloped hepatitis A virus. The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19 virus (pathogens of rubella).

Immunoglobulins like Fovepta have so far 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 Fovepta is used **the name and batch number of the medicine** are recorded in order to maintain a record of the batches used.

Taking other medicines together with Fovepta
Please tell your doctor or healthcare professional if your newborn has been given any other medicines.

Vaccinations

Fovepta can reduce the effectiveness of some vaccines (measles, rubella, mumps, chicken pox) for a period of up to 3 months.

You may have to wait at least 3 months after the injection of Fovepta before your newborn can have some vaccines.

Please tell your doctor about the treatment with Fovepta of your newborn prior to any vaccination.

Blood tests
Fovepta might affect the results of different blood tests (serological tests). Please tell your doctor about the treatment with Fovepta of your newborn prior to any blood test.

Pregnancy and breast-feeding

Not applicable

Driving and using machines
Not applicable

3. HOW TO USE FOVEPTA

Fovepta is intended for subcutaneous or intramuscular injection, means under the skin or into the muscle, and is given by a doctor/female doctor or a nurse/male nurse. The contents of one syringe are intended for use once only. **This medicine must not be injected into a blood vessel.**
In case bleeding disorders are known or the suspicion of bleeding disorders exists, the medicine should be given under the skin.

Fovepta is given to your newborn within 12 hours after birth. A hepatitis-B vaccination is highly recommended. The first dose of vaccine can be given on the same day as Fovepta, the injection being performed at different body sites.

If more Fovepta has been given as it should be
There are no known consequences of an overdose. However, contact your doctor, healthcare professional or pharmacist straight away for advice if more than the prescribed dosage of Fovepta has been given to your newborn.

4. POSSIBLE SIDE EFFECTS

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

If you notice any of the following side effects in your newborn, tell your doctor immediately:
- rash
- itching
- wheezing
- difficulty in breathing
- swelling of the eyelids, face, lips, throat or tongue
- low blood pressure, fast pulse

This can be an allergic reaction (hypersensitivity reaction) or a serious allergic reaction (anaphylactic shock).

The frequency regarding the side effects can not be estimated on the basis of the available data from clinical studies.

With other human immunoglobulin preparations the following side effects have been reported:
- At the injection site: swelling, sensitivity to pain, reddening, induration of the skin, local heating, itching and rash
- hypersensitivity
- anaphylactic shock / allergic shock
- headache
- accelerated pulse
- low blood pressure
- nausea
- vomiting
- skin reaction
- skin reddening
- itching
- joint pain

- fever
- malaise
- chills

Your newborn should be closely monitored during the injection. Attention should be paid to any symptoms occurring during the injection. If any side effects occur in the context of the injection you must speak to your doctor immediately.

Please tell your doctor, healthcare professional or pharmacist,
if any of the side effects listed gets serious in your newborn, *or* if you notice a side effect not listed in this leaflet.

5. HOW TO STORE FOVEPTA

- Keep out of the reach and sight of children.
- Do not use Fovepta after the expiry date which is stated on the outer carton and the syringe label after EXP. The expiry date refers to the last day of that month.
- Store and transport refrigerated (2°C-8°C).
- Do not freeze.
- Keep the container in the outer carton in order to protect from light.
- Fovepta must be brought to room temperature (approx. 23°C-27°C) before use. The solution should be administered immediately after opening the syringe.
- Do not use Fovepta if you notice that the solution is cloudy or has particles.
- Any unused medicine or waste material should be disposed of in accordance with local requirements.

6. FURTHER INFORMATION

What Fovepta contains

- The **active substance** of Fovepta is human hepatitis B immunoglobulin 500 IU/ml.
- Fovepta contains 150 mg/ml of human plasma protein of which at least 96 % is immunoglobulin G (IgG). The maximum immunoglobulin A (IgA) content is 6 mg/ml.
- The **other ingredients** are glycine and water for injections.

What Fovepta looks like and the contents of the pack

Fovepta is presented as a solution for injection provided in a pre-filled syringe (200 IU in 0.4 ml). The colour of the solution can vary from clear to pale yellow or light brown.

1 injection needle.

Marketing Authorisation Holder and Manufacturer

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THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY:

Method of administration

Fovepta should be administered via the subcutaneous or the intramuscular route.

Where simultaneous vaccination is necessary, the injections should be administered at different sites.

Special precautions

Ensure that Fovepta is not administered into a blood vessel, because of the risk of shock.

Fovepta contains a small quantity of 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 Fovepta against the potential risk of hypersensitivity reactions.

Rarely, human hepatitis B immunoglobulin can induce a fall in blood pressure with anaphylactic reactions, even in patients who have tolerated previous treatment with human immunoglobulin.

It is strongly recommended that when Fovepta is administered the name of the patient as well as the 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 Fovepta solution as any change in the electrolyte concentration or the pH may result in precipitation or denaturisation of the proteins.

Instructions for handling and disposal

Do not use Fovepta after the expiry date which is stated on the label and outer carton. The expiry date refers to the last day of that month.

Fovepta has to be brought to room or body temperature before use.

The solution has to 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 dosage regimen is recommended.

Prevention of hepatitis B in the newborn, of a hepatitis B virus carrier-mother

At birth or as soon as possible after birth (within 12 hours): 200 IU.
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 the same day as human hepatitis B immunoglobulin, however at different sites. In subjects who did not show an immune response (no measurable hepatitis B antibody titer) after vaccination, and for whom continuous prevention is necessary, administration of 8 IU/kg (0.16 ml)/kg body weight to children every 2 months can be considered; a minimum protective antibody titer is considered to be 10 mIU/mL.