

## Package leaflet: Information for the user

### PreHevbri suspension for injection Hepatitis B vaccine (recombinant, adsorbed)

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

#### Read all of this leaflet carefully before you receive this vaccine 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.
- If you get any 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 PreHevbri is and what it is used for
2. What you need to know before you receive PreHevbri
3. How PreHevbri is given
4. Possible side effects
5. How to store PreHevbri
6. Contents of the pack and other information

### 1. What PreHevbri is and what it is used for

PreHevbri is a vaccine which prevents infection caused by the hepatitis B virus. It is used in adults to protect from all known types of hepatitis B virus.

PreHevbri may also protect against hepatitis D which can only occur in people who have hepatitis B infection.

### What is hepatitis B

- Hepatitis B is an infectious illness of the liver caused by a virus. Hepatitis B virus infection can cause serious liver problems such as “cirrhosis” (scarring in the liver) or liver cancer.
- Some people infected with the hepatitis B virus become carriers, which means that they may not feel ill but continue to have the virus in their body and they can still infect other people.
- The disease spreads by the hepatitis B virus entering the body through contact with an infected person’s body fluids, such as in the vagina, blood, semen, or spit (saliva). A mother who is a carrier of the virus can also pass the virus to her baby at birth.
- The main signs of the illness include mild signs of flu (such as headache and fever, feeling very tired, dark urine, pale stools [faeces], and yellowing of the skin and eyes [jaundice]). However, some people with hepatitis B do not look or feel ill.

### How PreHevbri works

When a person is given the PreHevbri vaccine, it helps the body’s natural defence system (immune system) produce specific protection (antibodies) against the hepatitis B virus.

- PreHevbri contains a substance (called an ‘adsorbent’) which improves the body’s production of antibodies and makes the protection last for longer.
- A course of three injections of PreHevbri is required to provide full protection against hepatitis B.
- PreHevbri is not used to treat a person who is already infected with the hepatitis B virus including anyone who has previously been infected and who is now a carrier of the virus.
- PreHevbri is a ‘3-antigenic’ vaccine, which contains small amounts of the three antigens (pre-S1, pre-S2, S) from the ‘outer coating’ of the hepatitis B virus. This ‘outer coating’ is not infectious and cannot make you ill.

### 2. What you need to know before you receive PreHevbri

#### You must NOT receive PreHevbri:

- if you are allergic to the active substance or any of the other ingredients of this vaccine (listed in section 6). Signs of an allergic reaction may include breathing difficulty, swelling, light-headedness, fast heartbeat, sweating, and loss of consciousness.
- if you have ever previously had a sudden, life-threatening allergic reaction to any vaccine against hepatitis B.

You must not receive PreHevbri if either of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before receiving PreHevbri.

#### Warnings and precautions

- Your doctor, pharmacist or nurse will make sure that appropriate medical treatment is readily available in case you should develop a sudden and rare anaphylactic reaction (a very severe allergic reaction with symptoms such as breathing difficulty, swelling, light-headedness, fast heartbeat, sweating, and loss of consciousness) after you have been given the vaccine. This reaction may occur when any vaccine is injected, including PreHevbri. **Seek urgent medical attention** if you develop any of these symptoms after you are given the injection as this could be a life-threatening allergic reaction.
- Fainting can occur following, or even before, any needle injection, therefore tell the doctor, pharmacist or nurse if you fainted with a previous injection.
- If you are ill with a high fever, tell your doctor, pharmacist or nurse as they may delay the vaccination until you are feeling better. A minor infection such as a cold should not be a problem, but your doctor, pharmacist or nurse will decide if you could still be vaccinated.

- If you have low blood platelets or any blood-clotting disorders, then bleeding or bruising may occur after you are given the injection. Tell your doctor, pharmacist or nurse if you have any of these conditions.
- PreHevbri may not prevent hepatitis B infection if you already have an unrecognised hepatitis B infection at the time of vaccine administration.
- As with any vaccine, PreHevbri may not protect all people who are vaccinated.
- PreHevbri does not protect you against other liver infections such as hepatitis A, C, and E.
- If you are on dialysis for a kidney problem or if you have a weakened immune system your doctor may need to do a blood test to check if the vaccination has worked well enough to protect you against hepatitis B.

If you have any concerns or you are not sure about any of the above, talk to your doctor, pharmacist or nurse before receiving PreHevbri.

#### Children and adolescents

PreHevbri has not been fully tested in children under 18 years of age, it should not be used in this age group.

#### Other medicines and PreHevbri

Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines, including any other vaccine.

In addition to PreHevbri, you may be given an injection of hepatitis B ‘immuno-globulins’. This will give you immediate short-term protection against hepatitis B infection. If this happens your doctor, pharmacist or nurse will make sure that the two injections are given in different parts of the body.

#### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before being given this vaccine.

### The following information is intended for healthcare professionals only:

#### Storage

- Vials should be stored in a refrigerator (2°C to 8°C). Store in the original carton in order to protect from light.
- Do not freeze.

#### Preparation

- The vaccine should be used under aseptic conditions.
- The suspension is slightly white opaque when mixed. Upon settling, the solution is clear and colourless with a white deposit.
- The suspension should be visually inspected prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, discard the vaccine.
- The vial should be shaken well prior to administration.

#### Administration

- PreHevbri should be injected intramuscularly into the deltoid muscle.
- Do not inject PreHevbri into the gluteal muscle, or intradermally or intravascularly.
- Each vial is for single use only.
- PreHevbri must not be mixed with other medicinal products.

#### Disposal

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

It is unknown whether PreHevbri is excreted in human milk. A risk to the suckling child cannot be excluded. Discuss with your doctor or nurse whether the risks and benefits of breast-feeding your child outweigh the benefit of vaccination and whether you should stop breast-feeding.

#### **Driving and using machines**

PreHevbri is unlikely to have any effect on the ability to drive and use machines. If you feel tired, or have a headache or feel dizzy after having the vaccine, do not drive or use any machines until you feel well again.

#### **PreHevbri contain sodium and potassium**

This vaccine contains less than 1 mmol sodium (23 mg) per dose, i.e. that is to say is essentially 'sodium-free'.

This vaccine contains less than 1 mmol potassium (39 mg) per dose, i.e. that is to say is essentially 'potassium-free'.

### **3. How PreHevbri is given**

PreHevbri will be given to you as an injection by a doctor, pharmacist or nurse. The vaccine will usually be injected into a muscle in your upper arm.

You will be given a total of three injections.

Each injection will be given on separate visits:

- 1st injection: on a date agreed with your doctor, pharmacist or nurse;
- 2nd injection: 1 month after the 1st injection;
- 3rd injection: 6 months after the 1st injection.

The recommended dose for each injection is 10 micrograms (1 mL of suspension for injection).

#### **If you forget a scheduled dose of PreHevbri**

If you miss a scheduled dose, talk to your doctor, pharmacist or nurse to arrange another visit to receive the missed dose.

Make sure you receive the complete course of three injections or you may not be fully protected.

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

### **4. Possible side effects**

Like all vaccines, this vaccine can cause side effects, although not everybody gets them.

**Very common** (may affect more than 1 in 10 people):

- feeling very tired;
- pain or tenderness at the injection site;
- itching at the injection site;
- muscle pain;
- headache.

**Common** (may affect up to 1 in 10 people):

- diarrhoea;
- feeling or being sick;
- stomach pain;
- redness, bruising or swelling at the injection site;
- rash;
- dizziness;
- joint pain;
- fever.

**Uncommon** (may affect up to 1 in 100 people):

- swollen lymph nodes;
- hives or itchy skin;
- flushing or hot flushes.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this vaccine.

### **5. How to store PreHevbri**

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store vials in a refrigerator (2°C to 8°C). Store in the original package in order to protect from light. Do not freeze.

Do not throw away any vaccines via wastewater. Any unused medicinal product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What PreHevbri contains**

One dose (1 mL) contains:

- Active substances: 10 micrograms of hepatitis B surface antigens (S [83%], pre-S<sub>2</sub> [11%] and pre-S<sub>1</sub> [6%])<sup>1,2</sup>

<sup>1</sup> Adsorbed on 500 micrograms of Al<sup>3+</sup> as aluminium hydroxide, hydrated

<sup>2</sup> Produced in Chinese Hamster Ovary cells by recombinant DNA technology

- The other ingredients are sodium chloride, potassium chloride, disodium phosphate dodecahydrate, potassium dihydrogen phosphate, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), water for injections.

### **What PreHevbri looks like and contents of the pack**

PreHevbri is a clear, colourless suspension with a fine white deposit. When the vial is shaken the suspension forms a slightly white opaque suspension.

PreHevbri is supplied in vials containing 1 mL. Each vial is for single use only.

Packs of 1 or 10 single-dose vials are available.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

VBI Vaccines B.V.  
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#### **Manufacturer**

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#### **For any information about this vaccine, please contact the local representative of the Marketing Authorisation Holder**

Valneva UK Ltd  
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#### **This leaflet was last revised in January 2024.**