

H-B-VAX[®] II

Hepatitis B Vaccine (Recombinant)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about H-B-VAX II. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines and vaccines have risks and benefits. Your doctor has weighed the risks of you being given H-B-VAX II against the benefits they expect it will have for you.

If you have any concerns about being given this vaccine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What H-B-VAX II is used for

H-B-VAX II is a vaccine used to help prevent hepatitis B. The vaccine can be given to newborns, infants, children, teenagers and adults.

Hepatitis B is an infection of the liver caused by the hepatitis B virus (HBV). It can be caught by coming into contact with an infected person's blood, semen, vaginal secretions, saliva or other body fluids. For example, if these infected fluids enter your blood stream through a cut in your skin, you could become infected. Other situations that could lead to infection include:

- being born to a mother who carries the HBV
- sexual contact with someone who is infected

- living in the same house as someone who is infected
- close family contact, for example, sharing razors or toothbrushes
- having a job that involves exposure to human blood or body fluids, for example, some health care workers
- sharing needles for injecting drugs
- travelling to areas where hepatitis B is common

People who have hepatitis B may not look or feel sick when infected. In fact, a person could be infected by the virus six weeks to six months before symptoms occur. Some people develop mild, flu-like symptoms. Others may become very ill and extremely tired, develop yellowing of the skin and/or eyes (also called jaundice), dark urine and other symptoms that require hospitalisation.

Most people recover completely from the HBV infection. However, there are some people, particularly children, who may not have symptoms but continue to carry the virus in their blood. They are called chronic carriers. These chronic carriers are infectious and can spread the disease to others throughout their lives.

Babies who are infected with the HBV at birth, almost always go on to become chronic carriers. The infection at birth is silent, and the babies appear healthy and continue to remain healthy for many years. However, after 30, 40 or 50 years they can become unwell and develop the symptoms described above.

All chronic carriers run the risk of developing serious liver disease, such as cirrhosis (scarring of the liver) or liver cancer.

Vaccination is recommended for adults who are at substantial risk of hepatitis B virus infection.

H-B-VAX II works by causing your body to produce its own protection by making disease-fighting substances (antibodies) to fight the HBV. If a vaccinated person comes into contact with HBV, the body is usually ready, and produces antibodies to destroy the virus. However, as with all vaccines, 100% protection against hepatitis B cannot be guaranteed.

Because hepatitis B infection can go undetected for a long period of time, it is possible that an individual may already be infected at the time the vaccine is given. The vaccine may not prevent hepatitis B in these individuals.

Before you are given H-B-VAX II

When you or your child must not be given it

Do not have H-B-VAX II if:

- **you or your child have an allergy to H-B-VAX II or any of the ingredients listed at the end of this leaflet**
- **you or your child have an allergy to yeast**
- **the expiry date on the pack has passed.**

If the vaccine is used after the expiry date has passed, it may not work.

If you are not sure whether you should have H-B-VAX II, talk to your doctor.

Before you or your child are given it

Tell your doctor if:

1. you are pregnant or intend to become pregnant

It is not known whether the vaccine is harmful to an unborn baby when administered to a pregnant woman. Your doctor will give you H-B-VAX II only if it is clearly needed.

2. you are breast-feeding

It is not known whether H-B-VAX II passes into breast milk. Your doctor will discuss the possible risks and benefits of you being given H-B-VAX II while breast-feeding.

3. you or your child have any medical conditions, especially the following

- bleeding problems
- severe heart or lung disease
- diseases which decrease the immune system, for example, AIDS

H-B-VAX II may not work as well as it should if you or your child have diseases or conditions which decrease the body's immune defence system. Your doctor will decide whether or not to give the vaccine.

4. you or your child have an acute infection or a high temperature

Your doctor may decide to delay your injection of H-B-VAX II.

5. you or your child are undergoing dialysis

You may need to be given a higher dose of H-B-VAX II than normal.

6. you or your child have any allergies to any other medicines or any other substances, such as

foods, preservatives, latex rubber or dyes

7. you have previously been infected with hepatitis B virus.

If you have not told your doctor about any of the above, tell them before you or your child are given H-B-VAX II.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

H-B-VAX II may not work as well as it should if you or your child are taking medicines that decrease the immune system, such as corticosteroids (e.g. prednisone) or cyclosporin.

Your doctor will advise you if you are taking any of these or other medicines that decrease the immune system. Your doctor will decide whether or not to give the vaccine. You may need to be given a higher dose of H-B-VAX II than normal.

How H-B-VAX II is given

How much is given

Your doctor will decide on the dose of H-B-VAX II that you will be given. This depends on your age and other factors, such as if you are undergoing dialysis.

How it is given

H-B-VAX II is given as an injection, usually into your upper arm muscle by a doctor or trained nurse. For babies, the vaccine may be given into the upper thigh muscle.

For some people with bleeding problems, the vaccine may need to be given under the skin (subcutaneously). The vaccine should not be injected directly into veins (intravenously).

Vaccination schedule

H-B-VAX II is generally given as a total of three doses over six months. Each dose is given on a separate visit. The schedule is:

- 1st dose: at elected date
- 2nd dose: 1 month after first injection
- 3rd dose: 6 months after the first injection.

For children and teenagers aged 11 to 15 years, a total of two doses may be given instead of three. The schedule for two doses is:

- 1st dose: at elected date
- 2nd dose: 4 to 6 months after the first injection.

Vaccination is not necessary in children or teenagers who have received a course of hepatitis B vaccine before.

For babies born to mothers infected with HBV, the first dose of H-B-VAX II should be given at birth, or as soon thereafter as possible. In addition to the H-B-VAX II, an injection of hepatitis B immune globulin is also given.

It is important to return at the scheduled dates for the follow-up doses.

The duration of protective effect of H-B-VAX II is unknown. Therefore, it is not known whether a booster dose will be necessary.

If you miss a dose

If you miss a scheduled dose, talk to your doctor and arrange another visit as soon as possible.

After you have been given H-B-VAX II

Things you must do

Keep your follow-up appointments with your doctor or clinic.

It is important to have your follow-up doses of H-B-VAX II at the appropriate times to make sure the

vaccine has the best chance of providing protection against the hepatitis B virus.

Things to be careful of

Be careful driving or operating machinery until you know whether H-B-VAX II has affected you.

H-B-VAX II should not normally interfere with your ability to drive a car or operate machinery. However, H-B-VAX II may cause dizziness or light-headedness in some people. Make sure you know how you react to H-B-VAX II before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well during or after having had an injection of H-B-VAX II.

H-B-VAX II helps protect most people from hepatitis B, but it may have unwanted side effects in a few people. All medicines and vaccines 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 side effects.

Ask your doctor or pharmacist to answer any questions you may have.

In Children:

Tell your doctor if your child has any of the following and they are troublesome or ongoing:

- local reaction around the injection site such as soreness, redness and swelling
- fever
- smaller appetite than normal
- cold symptoms including runny nose, cough
- headache
- vomiting, diarrhoea

- irritability or tiredness, especially in infants aged from 0-1 years
- crying more than normal
- difficulty sleeping

These are the more common side effects that may occur in children aged 0-10 years. For the most part these have been mild.

Other people:

Tell your doctor if you notice any of the following and they worry you:

- a local reaction around the injection site such as pain, soreness, tenderness, itching, redness, swelling, warmth or a hard lump
- tiredness, weakness
- fever, sore throat, runny nose, cough
- nausea, feeling generally unwell
- diarrhoea
- headache

These are the more common side effects of H-B-VAX II. For the most part these have been mild.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:

- tingling of the hands or feet, sudden numbness or weakness in the legs or arms
- drooping eyelid or sagging muscles on one side of the face, also called Bell's palsy
- sudden dimming or loss of vision
- a seizure or convulsion, which may or may not be accompanied by a very high fever
- headache and fever, progressing to hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck and sensitivity to light.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects also reported include bleeding or bruising more easily than normal.

Allergic Reaction:

As with all vaccines given by injection, there is a very small risk of a serious allergic reaction.

Tell your doctor immediately or go to accident and emergency if you notice any of the following:

- dizziness, light-headedness
- skin rash, itchiness
- swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- painful, swollen joints, sometimes occurring days to weeks after vaccination

These are serious side effects. If you have them, you may have had a serious allergic reaction to H-B-VAX II. You may need urgent medical attention or hospitalisation. Most of these side effects occur within the first few hours of vaccination.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

Storage

H-B-VAX II is usually stored in the doctor's surgery or clinic, or at the pharmacy. However if you need to store H-B-VAX II:

- **Keep it where children cannot reach it.**
- **Keep it in the refrigerator, but not in the door compartment.**
- **Do not put H-B-VAX II in the freezer, as freezing destroys the vaccine.**

- **Keep the injection in the original pack until it is time for it to be given.**

Product description

What it looks like

H-B-VAX II comes in glass vials as a slightly white liquid. Three different vaccine doses are available:

- 5 microgram in 0.5 mL of liquid
- 10 microgram in 1 mL of liquid
- 40 microgram in 1 mL of liquid (This strength is intended for predialysis/dialysis patients only.)

H-B-VAX II also comes in prefilled syringes for the following vaccine doses:

- 5 microgram in 0.5 mL of liquid
- 10 microgram in 1 mL of liquid

Ingredients

The active ingredient of H-B-VAX II is the surface protein of the hepatitis B virus, derived from genetically engineered yeast cells. The vaccine is not infectious, and will not give you the hepatitis B virus.

Inactive ingredients:

- aluminium hydroxide
- sodium chloride
- borax
- formaldehyde
- potassium thiocyanate

H-B-VAX II is made without any human blood or blood products.

Supplier

H-B-VAX II is supplied in Australia by:

bioCSL Pty Ltd

63 Poplar Road

PARKVILLE VIC 3052

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Australian Register Numbers:

Glass vials:

5 microgram/0.5mL: AUST R 72347

10 microgram/mL: AUST R 90624

40 microgram/mL: AUST R 90623

Prefilled syringes:

5 microgram/0.5mL: AUST R 127244

10 microgram/mL: AUST R 127245