

HBvaxPRO®

hepatitis B Vaccine (Recombinant)

5 mcg hepatitis B surface antigen per 0.5 mL (without preservative)

10 mcg hepatitis B surface antigen per 1.0 mL (without preservative)

40 mcg hepatitis B surface antigen per 1.0 mL (This formulation is intended for predialysis/dialysis patients only (without preservative))

What is in this leaflet

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

All medicines and vaccines have risks and benefits. Your doctor has weighed the risks of you being given HBvaxPRO 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. You may need to read it again.

What HBvaxPRO is used for

HBvaxPRO 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.

There is no specific treatment for hepatitis B. Therefore, vaccination is the best way to help protect against infection and possible serious long-term disease.

HBvaxPRO 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.

HBvaxPRO will not protect against hepatitis caused by other agents or viruses (such as hepatitis A, hepatitis C, hepatitis D, hepatitis E).

Before you are given HBvaxPRO

When you or your child must not be given it

Do not have HBvaxPRO if:

- you have an allergy to HBvaxPRO or any of the ingredients listed at the end of this leaflet
- you 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 HBvaxPRO, 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 HBvaxPRO only if it is clearly needed.
2. you are breast-feeding
It is not known whether HBvaxPRO passes into breast milk. Your doctor will discuss the possible risks and benefits of you being given HBvaxPRO while breast-feeding.

3. you have any medical conditions, especially the following
 - bleeding problems
 - severe heart or lung disease
 - diseases which decrease the immune system, for example, AIDSHBvaxPRO may not work as well as it should if you or your child have diseases or conditions which decrease the body's immune defense system. Your doctor will decide whether or not to give the vaccine.
4. you have an acute infection or a high temperature
Your doctor may decide to delay your injection of HBvaxPRO.
5. you are undergoing dialysis
You may need to be given a higher dose of HBvaxPRO than normal.
6. you have any allergies to any other medicines or any other substances, such as foods, preservatives, latex rubber or dyes.

Use in Elderly – Hepatitis B vaccines may not be as effective in individuals 65 years of age and older, as they are with younger subjects.

If you have not told your doctor about any of the above, tell them before you are given HBvaxPRO.

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.

HBvaxPRO 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 HBvaxPRO than normal.

How HBvaxPRO is given

How much is given

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

How it is given

HBvaxPRO 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

HBvaxPRO 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: \geq 1 month after first injection
- 3rd dose: \geq 1 month after the second injection

For adolescents, 11 to 15 years of age, a two-dose series may be given according to the following schedule:

- First dose: at elected date
- Second dose: 4 to 6 months later

For babies born to mothers infected with HBV, the first dose of HBvaxPRO should be given at birth, or as soon thereafter as possible. In addition to the HBvaxPRO 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 HBvaxPRO 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 HBvaxPRO

Things you must do

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

It is important to have your follow-up doses of HBvaxPRO 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 HBvaxPRO has affected you.

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

Adverse Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well during or after having had an injection of HBvaxPRO.

HBvaxPRO helps protect most people from hepatitis B, but it may have unwanted adverse effects in a few people. All medicines and vaccines can have adverse 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.

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, especially in infants aged from 0-1 years

These are the more common adverse 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 adverse effects of HBvaxPRO. 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

These are serious adverse effects. You may need urgent medical attention. Serious adverse 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 nettlerash
- painful, swollen joints, sometimes occurring days to weeks after vaccination

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

Other adverse 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 adverse effects. You may not experience any of them.

Storage

HBvaxPRO is usually stored in the doctor's surgery or clinic, or at the pharmacy. However if you need to store HBvaxPRO:

- Keep it where children cannot reach it.
- Keep it in the refrigerator, but not in the door compartment.
- Do not put HBvaxPRO in the freezer, as freezing destroys the vaccine.
- Keep the injection in the original pack until it is time for it to be given.
- Protect from light

Product description

What it looks like

HBvaxPRO comes in glass vials as a slightly white liquid. Three different vaccine doses are available:

- 5.0 microgram in 0.5 mL of liquid (without preservative)
- 10 microgram in 1 mL of liquid (without preservative)
- 40 microgram in 1 mL of liquid (without preservative). (This strength is intended for predialysis/dialysis patients only).

This vaccine may contain traces of formaldehyde and potassium thiocyanate which are used during the manufacturing process.

Ingredients

The active ingredient of HBvaxPRO 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:

- sodium chloride
- sodium borate
- water for injection

Adjuvant

aluminium provided as amorphous aluminium hydroxyphosphate sulphate

HBvaxPRO is made without any human blood or blood products, or any other substances of human origin. It does not contain any infectious material.

Supplier

HBvaxPRO is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland
NEW ZEALAND.
Tel: 0800 500 673

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