H-B-VAX II®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this vaccine, speak to your doctor, nurse or pharmacist.

1. Why am I or my child being given H-B-VAX II?

H-B-VAX II contains recombinant Hepatitis B Vaccine and Hepatitis B surface antigen. H-B-VAX II is a vaccine used to help prevent hepatitis B.

For more information, see Section 1. Why am I or my child being given H-B-VAX II? in the full CMI.

2. What should I know before my child or I are given H-B-VAX II?

Do not use if you or your child have ever had an allergic reaction to H-B-VAX II, to yeast or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you or your child have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before my child or I are given H-B-VAX II? in the full CMI.

3. What if my child or I are taking other medicines?

Some medicines may interfere with H-B-VAX II and affect how it works.

A list of these medicines is in Section 3. What if my child or I are taking other medicines? in the full CMI.

4. How is H-B-VAX II given?

A doctor or nurse will give you or your child this vaccine as an injection, usually into the upper arm muscle. For babies, the vaccine may be given into the upper thigh muscle.

More instructions can be found in Section 4. How is H-B-VAX II given? in the full CMI.

5. What should I know after my child or I have been given H-B-VAX II?

Things you should do	• 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.
Driving or using machines	• 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.
Looking after your medicine	It is unlikely that you will be asked to store H-B-VAX II. If you are, keep it where children cannot reach it. Keep it in the refrigerator between 2°C and 8°C. Do not freeze this vaccine.

For more information, see Section 5. What should I know after my child or I have been given H-B-VAX II? in the full CMI.

6. Are there any side effects?

Common side effects include: 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

Serious side effects may include allergic reactions such as dizziness; light-headedness; 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.

For a complete list of side effects and more information, including what to do if you or your child have any side effects, see Section 6. Are there any side effects? in the full CMI.

H-B-VAX II

Active ingredient: *Hepatitis B Vaccine (recombinant) & hepatitis B surface antigen (recombinant)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using H-B-VAX II. **You should also speak to your doctor, nurse, or pharmacist if you would like further information or if you have any concerns or questions about using H-B-VAX II.**

Where to find information in this leaflet:

1. Why am I or my child being given H-B-VAX II?
2. What should I know before my child or I are given H-B-VAX II?
3. What if my child or I are taking other medicines?
4. How is H-B-VAX II given?
5. What should I know after my child or I have been given H-B-VAX II?
6. Are there any side effects?
7. Product details

1. Why am I or my child being given H-B-VAX II?

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.

What is Hepatitis B

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.

How does it work

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 Hepatitis B Virus (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.

2. What should I know before my child or I are given H-B-VAX II?

Warnings

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.

Check with your doctor if

- **you are pregnant or intend to become pregnant**
- **you are breast- feeding**
- **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.
- **you or your child have an acute infection or high temperature**

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

- **you or your child are undergoing dialysis**

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

- **you or your child have any allergies to any other medicines or any other substances, such as foods, preservatives, latex rubber or dyes**
- **you or you child 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. 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

Use in the elderly

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

3. What if my child or I are taking other medicines?

Tell your doctor, nurse, or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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.

Check with your doctor, nurse, or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect H-B-VAX II.

4. How is H-B-VAX II given?

How much will you be given

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

How is it 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).

When is it given

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 immunoglobulin 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 or your child miss a dose of H-B-VAX II

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

5. What should I know after my child or I have been given H-B-VAX II?

Things you should 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.

Driving or using machines **Be careful before you drive or use any machines or tools until you know how H-B-VAX II affects 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.

Looking after your medicine

It is unlikely that you will be asked to store H-B-VAX II. 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.
- Protect from light.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines, including vaccines, can have side effects. If you or your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse, or pharmacist if you have any further questions about side effects.

Side effects in Children

Side Effects in Children	What to do
• 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	**Speak to your doctor if you have any of these less serious side effects and they worry you or are ongoing.** These are the more common side effects that may occur in children aged 0-10 years. For the most part these have been mild.

Common Side Effects in Adults

Common Side Effects	What to do
• 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	**Speak to your doctor if you have any of these common side effects and they worry you.** These are the more common side effects of H-B-VAX II. For the most part these have been mild.

Serious Side Effects

Serious Side Effects	What to do
• 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. As with all vaccines given by injection, there is a very small risk of a serious allergic reaction. • 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	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** These are serious side effects. You may need urgent medical attention. Serious side effects are rare. **These are serious side effects. If you or your child have them, you may have had a serious allergic reaction to H-B-VAX II and may need urgent medical attention or**

Serious Side Effects	What to do
	hospitalisation. Most of these side effects occur within the first few hours of vaccination.

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

Tell your doctor or pharmacist if you or your child notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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

Reporting side effects

After you have received medical advice for any side effects you or your child experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What H-B-VAX II contains

Active ingredient^ (main ingredient)	Surface protein of the hepatitis B virus, derived from genetically engineered yeast cells. *
Other ingredients (inactive ingredients)	Aluminium (as amorphous aluminium hydroxyphosphate sulfate) Sodium chloride Borax

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

*The protein in H-B-VAX II is not alive and cannot give you the hepatitis B virus.

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

Do not take this medicine if you are allergic to any of these ingredients.

What H-B-VAX II looks like

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

5 micrograms in 0.5 mL of liquid (AUST R 72347)

10 micrograms in 1 mL of liquid (AUST R 90624)

40 micrograms in 1 mL of liquid (AUST R 90623)

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

5 micrograms in 0.5 mL of liquid (AUST R 127244)

10 micrograms in 1 mL of liquid (AUST R 127245)

Who distributes H-B-VAX II

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park NSW 2113

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