

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

RECOMBIVAX HB®

(hepatitis B vaccine [recombinant])

Read this carefully before you start taking **Recombivax HB** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Recombivax HB**.

What is RECOMBIVAX HB® used for?

RECOMBIVAX HB® (hepatitis B vaccine [recombinant]) is an injectable vaccine that helps prevent infection of the liver caused by hepatitis B virus.

The vaccine can be administered to infants, children, adolescents, and adults.

How does RECOMBIVAX HB® work?

Your doctor has recommended or administered RECOMBIVAX HB® to help protect you or your child against hepatitis B, an infection of the liver caused by the hepatitis B virus (HBV).

You could catch this disease by coming into contact with an infected person's blood, semen, vaginal secretions, or other body fluids. For example, if these infected fluids enter your blood stream through a cut, you could become infected. Other circumstances that could lead to infection include:

- being born to a mother who carries the HBV
- living in the same household as someone who carries the HBV
- sexual/close contact with someone who is infected
- having a job that involves exposure to human blood or body fluids
- sharing needles for injecting drugs
- traveling to areas of high frequency of HBV disease

Individuals 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 individuals develop mild, flu-like symptoms. Others may become very ill and extremely tired, develop jaundice (yellow appearance of the skin, eyes, etc.), dark urine and other symptoms that require hospitalization.

Most people recover completely from HBV infection. However, there are some individuals, 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. All chronic carriers run the risk of developing life threatening liver disease, cirrhosis, or liver cancer.

What are the ingredients in RECOMBIVAX HB®?

Medicinal ingredients:

Pediatric presentation: Each 0.5 mL dose contains 5 mcg of hepatitis B surface antigen as the active ingredient.

Adult presentation: Each 1 mL dose contains 10 mcg of hepatitis B surface antigen as the active ingredient.

Adult dialysis presentation: Each 1 mL dose contains 40 mcg of hepatitis B surface antigen as the active ingredient.

Non-medicinal ingredients:

Aluminum (as amorphous aluminum hydroxyphosphate sulfate), sodium chloride and sodium borate. Each dose contains less than 1% yeast protein.

The vial stopper and the syringe plunger stopper and tip cap contain latex.

RECOMBIVAX HB® comes in the following dosage forms:

RECOMBIVAX HB® is supplied as a slightly cloudy, white suspension for injection in glass vials. Three formats are available:

- Pediatric: single-dose vials and prefilled syringes containing 5 mcg hepatitis B surface antigen in 0.5 mL (thimerosal-free)
- Adult: single-dose vials and prefilled syringes containing 10 mcg hepatitis B surface antigen in 1.0 mL (thimerosal-free)
- Adult dialysis: single-dose vials containing 40 mcg hepatitis B surface antigen in 1 mL (thimerosal-free).

Do not use RECOMBIVAX HB® if:

RECOMBIVAX HB® should not be used by anyone who is hypersensitive to this drug or to any ingredient in the formulation or component of the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RECOMBIVAX HB®. Talk about any health conditions or problems you may have, including if :

- you or your child are allergic to any component of the vaccine
- you or your child are allergic to latex
- you or your child have or have had any medical problem, including any allergies
- you are pregnant or intend to become pregnant

Use in children

RECOMBIVAX HB® can be used in newborns, infants, and children of all ages.

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.

Use in pregnancy and breast-feeding

It is not known whether the vaccine is harmful to an unborn baby when administered to a pregnant woman. If you are pregnant, you should be vaccinated with RECOMBIVAX HB® only if your doctor decides it is clearly needed.

Tell your doctor if you are breast feeding.

Other warnings you should know about:

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.

It can be expected that hepatitis D will also be prevented by immunisation with RECOMBIVAX HB as hepatitis D does not occur in the absence of hepatitis B infection.

The vaccine will not prevent infection caused by other agents such as hepatitis A, hepatitis C and hepatitis E and other pathogens known to infect the liver.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with RECOMBIVAX HB®:

In general, simultaneous administration of certain childhood vaccines has not decreased their effectiveness or increased their side effects.

How to take RECOMBIVAX HB®:

RECOMBIVAX HB® will be given to you or your child by a healthcare professional in a healthcare setting.

Usual dose:

RECOMBIVAX HB® is given by injection. A three-dose series should be given according to the following schedule:

- First dose: at elected date
- Second dose: >1 month after first injection
- Third dose >1 month after 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

NOTE: For infants born to mothers infected with HBV, the first dose of the hepatitis B vaccination series should be given at birth, or as soon thereafter as possible, in addition to an injection of hepatitis B immune globulin.

At present, it is not known whether a booster dose will be necessary. See your doctor for more details.

Overdose:

If you think you, or a person you are caring for, have taken too much RECOMBIVAX HB[®], contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using RECOMBIVAX HB[®]?

These are not all the possible side effects you may have when taking RECOMBIVAX HB[®]. If you experience any side effects not listed here, tell your healthcare professional.

Any vaccine may have unintended or undesirable effects, so-called side effects. RECOMBIVAX HB[®] is generally well tolerated. The side effects seen in children, adolescents, and adults include injection-site reactions such as soreness, redness, swelling, itching, bruising, warmth and a hard lump. Generalized reactions include fatigue, headache, fever, nausea, diarrhea, and vomiting. Serious side effects occur less frequently and can include allergic reactions, certain severe types of rash, joint pain, muscle disorders, and nerve disorders such as Guillain-Barré Syndrome, seizure, or convulsion accompanied by a very high fever, and fainting. Other side effects also reported include bleeding or bruising more easily than normal.

Your doctor has a more complete list of side effects.

Tell your doctor promptly about these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

In addition, tell your doctor if you experienced any symptoms that suggest an allergic reaction after any dose in the vaccination series.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Merck Canada Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your

province/territory (<http://www.phac-aspc.gc.ca/im/aefi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store refrigerated at 2-8°C. Do not freeze. Protect from light.

All vaccines must be discarded after the expiration date.

Keep out of reach and sight of children.

If you want more information about RECOMBIVAX HB®:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.merck.ca, or by calling 1-800-567-2594.

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