

PART III: CONSUMER INFORMATION

RECOMBIVAX HB[®]

(hepatitis B vaccine [recombinant])

This leaflet is part III of a three-part "Product Monograph" published when RECOMBIVAX HB[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RECOMBIVAX HB[®]. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine is 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.

What it does:

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.

When it should not be used:

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.

What the medicinal ingredient is:

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

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

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

What the important nonmedicinal ingredients are:

Aluminum (as amorphous aluminum hydroxyphosphate), sodium chloride and sodium borate. The vaccine may contain <1% yeast protein.

The vial stopper contains latex.

What dosage forms it comes in:

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

- Pediatric: single-dose vial containing 5 µg hepatitis B surface antigen in 0.5 mL (thimerosal-free)
- Adult: single-dose vial containing 10 µg hepatitis B surface antigen in 1.0 mL (thimerosal-free)
- Adult dialysis: single-dose vial containing 40 µg hepatitis B surface antigen in 1 mL (thimerosal-free).

WARNINGS AND PRECAUTIONS

Before you or your child receive RECOMBIVAX HB[®], it is very important to tell your healthcare provider:

- if you or your child are allergic to any component of the vaccine
- if you or your child are allergic to latex
- about any medical problem you or your child have or have had, including any allergies
- if 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 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.

Can I drive or operate machinery after vaccination with RECOMBIVAX HB[®]?

RECOMBIVAX HB[®] should not ordinarily interfere with your ability to drive or operate machinery. However, as with any vaccination, it is advisable to wait in your doctor's office about 20 minutes after vaccination in case an immediate allergic reaction develops.

Other Considerations

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.

INTERACTIONS WITH THIS VACCINE

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

PROPER USE OF THIS VACCINE

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:

In case of overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Your doctor will decide when to give the missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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.

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.

HOW TO STORE IT

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

All vaccines must be discarded after the expiration date.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects information on serious and unexpected adverse events following vaccination. If you suspect you have had a serious or unexpected event following receipt of a vaccine you may notify the Public Health Agency of Canada:

By toll-free telephone: 866-844-0018
By toll-free fax: 866-844-5931
E-mail: CAEFI@phac-aspc.gc.ca

By regular mail:
The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road
Ottawa, ON K1A 0K9
A/L 6502A

or Merck Canada Inc. by:

Toll-free telephone: 1-800-567-2594
Toll-free fax: 1-877-428-8675
By regular mail:
Merck Canada Inc.
P.O. Box 1005
Pointe-Claire - Dorval, QC H9R 4P8

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.merck.ca> or by contacting the sponsor, Merck Canada Inc., at: 1-800-567-2594.

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