

Ministry of Health and Long-Term Care

Interim Use of Publicly Funded Engerix-B[®] Vaccine for Renal Dialysis Patients

This document provides interim guidance on the use of Engerix-B[®] for renal dialysis patients who would have received Recombivax HB[®] Dialysis vaccine.

Q1: Why is Engerix-B[®] replacing the Recombivax HB[®] Dialysis vaccine?

Merck Canada Inc. manufactures Recombivax HB[®] Dialysis, a high dose (40µg/ml) hepatitis B (HB) vaccine specifically for adult dialysis patients. At this time, there is a global shortage of this vaccine that is expected to continue into early 2020.

Ontario's supply of Recombivax HB[®] Dialysis has now been depleted. Ontario continues to have an adequate supply of Engerix-B[®] vaccine (GSK) available.

Q2: Are HB vaccines interchangeable?

As per the Canadian Immunization Guide (CIG), it is recommended that a hepatitis B vaccination series should be completed with the same product that was used to initiate the series. However, the CIG states that monovalent HB vaccines can be used interchangeably. In making their decision on completing a vaccine series, health care providers should consult the CIG and the vaccine product monograph for dosage and schedules by age group.

Q3: Is Engerix-B[®] a new vaccine in the Ontario program?

Currently, Engerix-B[®] is used for the school-based HB immunization program as well as the high-risk HB immunization program in Ontario. Due to the global shortage of Recombivax HB[®] Dialysis, Engerix-B[®] is the only HB vaccine currently available in Ontario.

Q4: Does the publicly funded Engerix-B[®] vaccine formulation contain the same antigen content as publicly funded Recombivax HB[®] Dialysis vaccine?

Engerix-B[®] vaccine is available in 0.5ml and 1.0ml formulations. Each formulation has 20µg/ml of HB surface antigen.

Recombivax HB[®] Dialysis vaccine is available as a 1.0ml adult formulation, with 40µg/ml of HB surface antigen.

Q5: How many doses of Engerix-B[®] are recommended for optimal protection against HB virus (HBV) in adult renal patients?

The CIG recommends a 4-dose schedule using Engerix-B[®] vaccine (40µg per dose) for adults.

Table 1 below outlines the completion of HB immunization series for eligible individuals who have either not initiated the HB immunization series or have received 1 or 2 doses of Recombivax® HB Dialysis vaccine.

Table 1: Completion of HB vaccine series with Engerix-B® vaccine for renal patients

Number of Recombivax HB® Dialysis Doses Received	Completing the HB series with Engerix-B® (double dose) for renal patients using a 4-dose series as recommended by NACI
0 doses received	0, 1, 2, and 6 months
1 dose received	1, 2, and 6 months
2 doses received	2, and 6 months
<ul style="list-style-type: none"> • A double dose of Engerix-B® vaccine (i.e., 2 doses) is required to equate to 1 dose of Recombivax HB® Dialysis adult formulation. • As per the Publicly Funded Immunization Schedules for Ontario - December 2016, the ministry will publicly fund 2 doses of a 3-dose series of HB dialysis formulation vaccine. • Given Engerix-B® is a 4 double-dose series for immunizing adult dialysis patients, the ministry will publicly fund up to 6 doses of Engerix-B® vaccine. 	

For renal dialysis patients less than 20 years of age, please see the CIG for dosing and scheduling recommendations.

Q6: How many doses of Engerix-B® vaccine are publicly funded through Ontario’s immunization program for adults on renal dialysis who would have received less than 3 doses of Recombivax HB® Dialysis?

Adults on renal dialysis who have received less than 3 doses of the Recombivax HB® Dialysis adult vaccine formulation are able to receive up to 6 doses (20µg/ml x 2 doses) of Engerix-B® through Ontario’s publicly funded HB immunization program.

Q7. Is a booster HB vaccine needed after completion of the high dose HB immunization series?

Renal patients who received an HB vaccination series should have their anti-HBs titres evaluated annually. If their serology result falls below 10 IU/L, a booster dose should be provided. Additional information can be found in the CIG.

Engerix-B® can be administered for the booster dose. The booster should contain the same HB surface antigen content as the original series (e.g., 40µg per dose for renal dialysis patients).