



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 127244 H-B-VAX II hepatitis B vaccine recombinant preservative-free paediatric 5 microgram/0.5mL injection pre-filled syringe

**ARTG entry for** Medicine Registered

**Sponsor** Merck Sharp & Dohme (Australia) Pty Ltd

**Postal Address** North Ryde Post Business Centre, Locked Bag 2234, NORTH RYDE BC, NSW, 1670  
Australia

**ARTG Start Date** 10/08/2006

**Product Category** Medicine

**Status** Active

**Approval Area** Drug Safety Evaluation Branch

### Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

### Products

#### 1 . H-B-VAX II hepatitis B vaccine recombinant preservative-free paediatric 5 microgram/0.5mL

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/09/2023 10:08:02 AM
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#### Permitted Indications

No Permitted Indications included on Record

#### Indication Requirements

No Indication Requirements included on Record

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

For use in the immunisation against infection caused by all known subtypes of hepatitis B virus. INDICATIONS AS AT 17 NOVEMBER 2000: H-B-Vax II is indicated for immunisation against infection caused by all known subtypes of Hepatitis B virus. Adolescent vaccination is not necessary for children who have received a primary course of hepatitis B vaccine. Vaccination is recommended in adults who are at substantial risk of hepatitis B virus infection and have demonstrated or judged to be susceptible. Vaccination of individuals who have antibodies against hepatitis B virus from a previous infection is not necessary.

#### Warnings

See Product Information and Consumer Medicine Information for this product

#### Additional Product information

#### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Syringe	Glass Type I Clear	3 Years	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light Refrigerate Do not Freeze

#### Pack Size/Poison information

Pack Size	Poison Schedule
1 x 0.5mL syringe	(S4) Prescription Only Medicine
10 single use syringes	(S4) Prescription Only Medicine

#### Components

##### 1 . Medicine Component

<b>Dosage Form</b>	Injection, suspension
<b>Route of Administration</b>	Intramuscular
<b>Visual Identification</b>	Slightly opalescent white liquid

Public Summary



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**Active Ingredients**

Hepatitis B surface antigen recombinant 5 microgram

**Other Ingredients (Excipients)**

aluminium  
borax  
sodium chloride  
water for injections

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Public Summary