



NEONATAL MEDICATION GUIDELINE			
HEPATITIS B VACCINE			
Scope (Staff):	Nursing, Midwifery, Medical and Pharmacy Staff		
Scope (Area):	KEMH NICU, PCH NICU, NETS WA, KEMH and OPH Postnatal Clinical Areas		
This document should be read in conjunction with the <u>Disclaimer</u> .			

Quick Links			
<u>Dose</u>	Preparation & Administration	Side Effects & Interactions	Monitoring

### Restrictions

# **Formulary: Unrestricted**

# Description

Hepatitis B surface antigen induces protective antibody against the Hepatitis B virus (Anti-HBs). For use as part of the National Immunisation Program for prevention of Hepatitis B infection. For use in infants born to Hepatitis B positive mothers.

NB: Parent/guardian consent is to be obtained prior to administration of all vaccinations

#### **Presentation**

Unit dose syringe: H-B-Vax II Paediatric Preservative-free 0.5mL (5 micrograms)

**Unit dose syringe:** ENGERIX-B Paediatric Thiomersal-free 0.5mL (10 micrograms)

The Engerix-B and H-B-Vax II vaccines are manufactured by different processes, and the hepatitis B surface antigen content of an 'equivalent' dose of these vaccines is different. Switching vaccine brands during the vaccine regimen is not recommended.

Hepatitis B vaccine is a component of <u>Infanrix Hexa®</u> and is administered in this form at 2, 4 and 6 month doses.

# **Storage**

Refrigerate – do not freeze

#### Dose

Intramuscular: 0.5mL

# For preterm infants <32 weeks of age and/or birth weight <2000g:

If infant's weight is less than 1000g - omit birth dose and give first dose at 2 months of age.

<u>Dose</u>	<u>Age</u>
1 <sup>st</sup>	At birth or no later than 7 days of age
2 <sup>nd</sup>	2 months (as <u>Infanrix Hexa®</u> )
3 <sup>rd</sup>	4 months (as Infanrix Hexa®)
4 <sup>th</sup>	6 months (as Infanrix Hexa®)
5 <sup>th</sup>	12 months if antibody titre is low

# All other infants:

Dose Number	Age
1 <sup>st</sup>	At birth or no later than 7 days of age
2 <sup>nd</sup>	2 months (as <u>Infanrix Hexa®</u> )
3 <sup>rd</sup>	4 months (as Infanrix Hexa®)
4 <sup>th</sup>	6 months (as Infanrix Hexa®)

# For Infants of Hepatitis B positive mothers on the day of birth:

IM hepatitis B Immunoglobulin 100 units should be administered in conjunction with Hepatitis B Vaccine.

Administer into the opposite thigh.

# **Administration**

### Intramuscular Injection

For administration by intramuscular injection ONLY

Administer the entire reconstituted vial volume (0.5 mL) by intramuscular injection (IMI) to the anterolateral aspect of the thigh (slowly to reduce pain).

# **Compatible Fluids**

Do not combine with any other fluids or vaccinations

#### **Side Effects**

Common: Pain, redness or swelling at injection site, transient fever

Serious: allergic reactions including anaphylaxis

# **Monitoring**

Observe all patients for at least 15 minutes after vaccination.

The potential risk of apnoea and the need for respiratory monitoring for 48-72 hours should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

Monitor temperature – Do not give during febrile illness or acute infection

Hepatitis B surface antigens and hepatitis B surface antibodies should be measured in infants born to mothers with chronic hepatitis B infection 3 to 12 months after completing the primary vaccine course.

### Comments

Infanrix hexa® **must be reconstituted**. Add the entire contents of the syringe to the vial and shake until the pellet completely dissolves. Use reconstituted vaccine as soon as practicable. If it must be stored, hold at room temperature for no more than 8 hours.

Hepatitis B vaccine is recommended for all children. If the monovalent dose at birth is missed, vaccination against Hepatitis B should be continued with a multivalent vaccine following the routine schedule.

Hepatitis B Immunoglobulin is to be accessed from Pathology

# Related Policies, Procedures & Guidelines

National Immunisation Program Schedule

Western Australian Immunisation Schedule

#### **CAHS Clinical Practice Guidelines:**

**Immunisations** 

#### **WNHS Clinical Practice Guidelines:**

Hepatitis B Virus (HBV): Care of the infant born to HBV positive women

Maternal Hepatitis B Virus (HBV) Quick Reference Guide

Vaccinations

#### **WNHS Transfusion Medicine Protocol:**

Immunoglobulin Products

# WNHS Medication Management Framework Policy and Guideline:

Cold Chain Management for Medications and Vaccines

#### **CAHS Policy:**

**Medication Refrigerators and Freezers** 

#### References

Australian Medicines Handbook. Hepatitis B vaccine. In: Australian Medicines Handbook [Internet]. Adelaide (South Australia): Australian Medicines Handbook; 2021 [cited 2021 Nov 9]. Available from: <a href="https://amhonline.amh.net.au/">https://amhonline.amh.net.au/</a>

MIMS Australia. Engerix-B Vaccine paediatric formulation. In: MIMS Online [Internet]. St Leonards (New South Wales): MIMS Australia; 2016 [cited 2021 Nov 9]. Available from: <a href="https://www.mimsonline.com.au">https://www.mimsonline.com.au</a>

MIMS Australia. H-B-Vax II paediatric formulation. In: MIMS Online [Internet]. St Leonards (New South Wales): MIMS Australia; 2016 [cited 2021 Nov 9]. Available from: <a href="https://www.mimsonline.com.au">https://www.mimsonline.com.au</a>

The Australian Immunisation Handbook. Last updated October 2021 Available from: https://immunisationhandbook.health.gov.au/vaccine-preventable-diseases/hepatitis-b

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	Std 2: Partnering with Consumers			Std 6: Communicating for Safety			
	Std 3: Preventing and Controlling Healthcare Associated Infection			Std 7: Blood Management			
	Std 4: Medication Safety		Std 8: Recognising and Responding to Acute Deterioration				
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The health impact upon Aboriginal people has been considered, and where relevant incorporated and appropriately addressed in the development of this document (insert ISD Number). (Please refer to the Aboriginal Health Impact Statement and Declaration for Department of Health and Health Service Provider Guidelines – please delete once you have completed this).

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