



Hepatitis B Vaccine (rDNA) (Adult)

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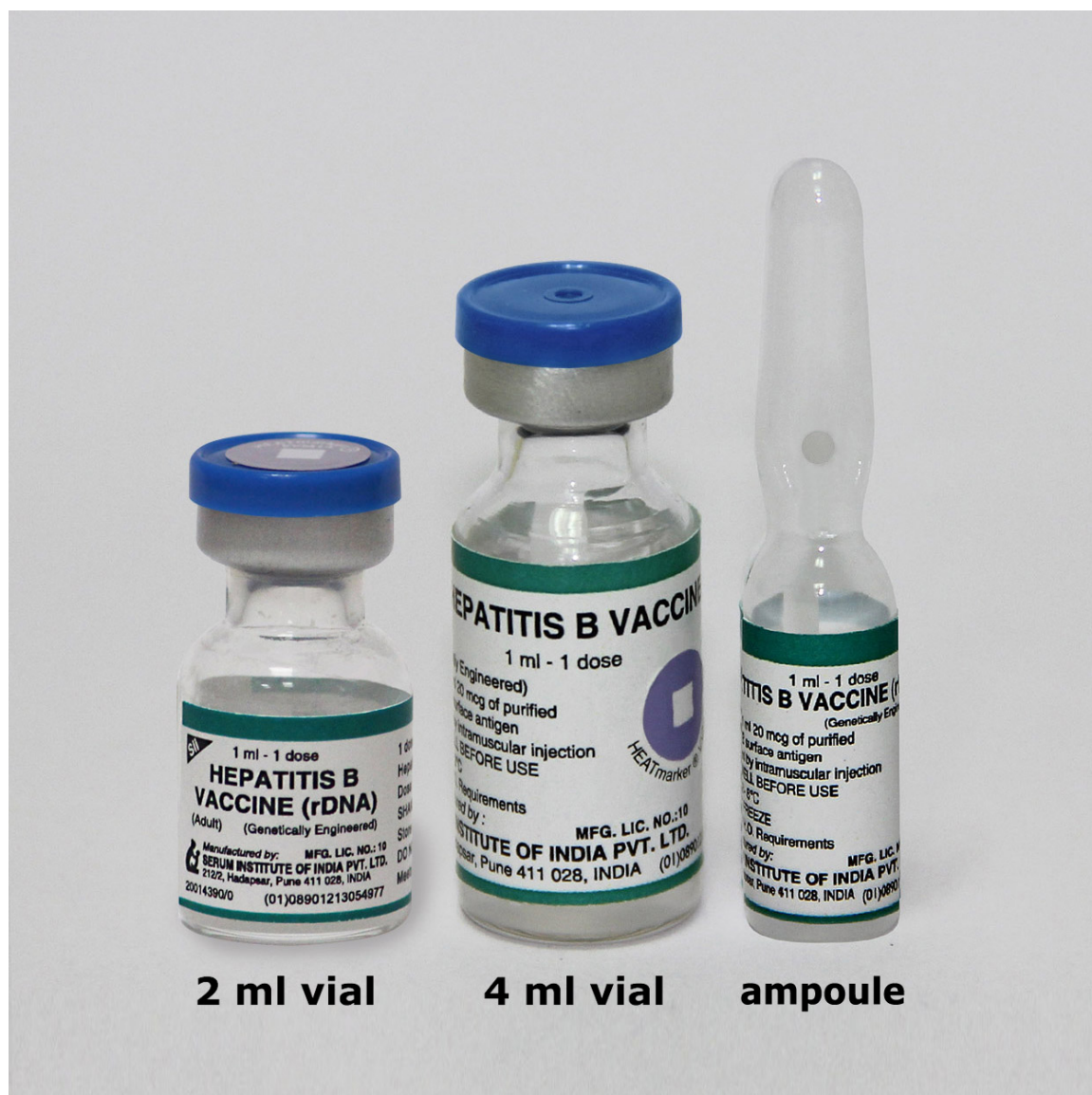
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Product overview

Type:	Hepatitis B
Commercial Name:	Hepatitis B Vaccine (rDNA) (Adult)
Manufacturer:	Serum Institute of India Pvt. Ltd.
Country:	India

URL:	http://www.seruminstitute.com/ [http://www.seruminstitute.com/]
Responsible NRA:	Central Drugs Standard Control Organization
Country:	India
URL:	www.cdsc.nic.in [http://www.cdsc.nic.in]
Bulk Supplier:	Not applicable

Prequalification

Prequalification Status:	Current
Effective Date:	12/11/2004

Product description

Pharmaceutical Form:	Liquid: ready to use
Presentation:	Ampoule or Vial
Number of Doses:	1
Diluent:	Not Applicable
Route of Administration:	Intramuscular
Shelf Life:	36 months at storage temperature: 2-8°C
Vaccine Vial Monitor:	Type 30
Secondary Packaging:	a. Carton of 50 vials (50 doses) [Dimensions 18.5 x 9.5 x 5.0 cm (4 ml)]; b. Carton of 50 vials (50 doses)[Dimensions: 18.5 x 9.5 x 4.0 cm (2 ml)]; c. Carton of 50 ampoules (50 doses) [Dimensions: 14.5 x 6.0 x 7.0 cm]
Tertiary Packaging:	a. Box of 24 cartons of 50 vials (1200 vials/1200 doses) [Dimensions: 60 x 48 x 36 cm]; b. Box of 36 cartons of 50 vials (1800 vials/ 1800 doses) [Dimensions: 60 x 48 x 48.5 cm]; c. Box of 36 cartons of 50 ampoules (1800 ampoules/1800 doses) [Dimensions: 60 x 48 x 41 cm]
Cold Chain Volume	a. 17.575 (40 mm vial); b.14.06 (30 mm vial) c.12.18 (ampoules) cm ³ /dose (in secondary packaging)
Preservative:	thiomersal with concentration: 0.005%
Handling of opened multi-dose vials:	Not Applicable.

Other presentations for this vaccine:

	Presentation	No. of Doses
Hepatitis B Vaccine (rDNA) (Adult) [/pqweb/content/hepatitis-b-vaccine-rdna-adult]	Vial	10

Attachments



pq_132_HepB(adult)_1dose_SII_vials+ampoule_image.jpg

Container Photo

pq_131_132_133_134_HepB_SII_PI_V5.pdf

Package Insert

Remark:

cold chain volume (cc)/dose: 17.575 (vial); 12.18 (ampoule)

Ampoule does not hold Vaccine Vial Monitor (VVM)

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