

**Corporate Plant  
Format**

|                       |                     |                 |        |
|-----------------------|---------------------|-----------------|--------|
| <b>Title</b>          | Artwork Format      |                 |        |
| <b>Format No.</b>     | 2002-0001-F0003-002 |                 |        |
| <b>Effective Date</b> | 30/07/2024          | <b>Page No.</b> | 1 of 1 |

**(SII) HEPATITIS B VACCINE (rDNA)**  
(Paediatric) Suspension for Injection (Genetically Engineered)

Each dose of 0.5 ml contains:  
10 mcg of purified Hepatitis B surface antigen  
Adsorbed on Aluminium hydroxide ( Al<sup>+++</sup> )  
0.25 mg to 0.40 mg  
Preservative : Thiomersal 0.005%  
Produced in *Hansenula polymorpha* (yeast)  
Dose : 0.5 ml by intramuscular injection  
Store at 2-8°C. DO NOT FREEZE.  
SHAKE WELL BEFORE USE.  
Meets W.H.O. Requirements.

**Manufactured by :** **SERUM INSTITUTE OF INDIA PVT. LTD.**  
S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110,  
113-114, 168-170 (M), Hadapsar, Pune 411 028, INDIA

**50 x 1 dose**

WARNING: RISK OF SENSITIZATION  
IN RELATION TO THIOMERSAL AND  
OTHER PRESERVATIVES  
Controlled Medicine Ubat terkawal  
Keep medicine out of reach of children.  
Jauhi ubat-ubatan daripada kanak-kanak

20007725/01

**MFG. LIC. NO.: 10**  
**SERUM INSTITUTE OF INDIA PVT. LTD.**  
S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110,  
113-114, 168-170 (M), Hadapsar, Pune 411 028, INDIA

**M. A. holder:**  
**SM Pharmaceuticals Sdn. Bhd.**  
Lot 88, Sungai Petani Industrial Estate,  
08000, Sungai Petani, Kedah, Malaysia  
MAL. No.: MAL 20091870AZ

**B. NO. :** Unvarnished area for  
batch details overprinting  
100 mm x 27 mm

**MFG. :**

**EXP. :**

|                                                    |                    |                                                                                                                                                                                                               |                                          |                       |
|----------------------------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|-----------------------|
| Reason for issue: SII logo and address revised     |                    | Specification: Self Adhesive Label<br>To be printed on chromo art paper 80 gsm with release paper of 62 gsm supplied in roll form. Aqua varnish coating on entire label except unvarnished overprinting area. |                                          |                       |
| Customer: Malaysia                                 |                    |                                                                                                                                                                                                               |                                          |                       |
| Product: <b>HEPATITIS B VACCINE (rDNA)</b><br>Name |                    | Paediatric<br>50 x 1 dose vial                                                                                                                                                                                | Colour: Pantone Process Blue C and Black |                       |
| Item Code number: 20007725/01                      |                    | Specification No.:                                                                                                                                                                                            |                                          | Artwork made to: 100% |
| Supersedes Item Code: 20007725/0                   |                    |                                                                                                                                                                                                               | Dimensions: 100 x 90 mm                  |                       |
| Prepared By                                        | Reviewed By        | Approved By                                                                                                                                                                                                   |                                          | Authorized By         |
| PACKAGING<br>DEVELOPMENT                           | QUALITY<br>CONTROL | REGULATORY<br>AFFAIRS                                                                                                                                                                                         | CLINICAL RESEARCH &<br>PHARMACOVIGILANCE | QUALITY<br>ASSURANCE  |