


Corporate Plant Format


Title	Artwork Format		
Format No.	2002-0001-F0003-000		
Effective Date	09/11/2020	Page No.	1 of 1



Rotavirus Vaccine, Live Attenuated (Oral)
(Freeze-Dried)

50 x 2.5 ml - 1 dose vials

Each dose of 2.5 ml contains :
 Live Attenuated Bovine - Human Rotavirus Reassortant
 [G1, G2, G3, G4 and G9]* $\geq 10^{5.6}$ FFU / Serotype
 Reconstitute with 2.5 ml of Diluent for Rotavirus Vaccine, (Citrate Bicarbonate Buffer)
 Dose: 2.5 ml by oral administration only.
 *Grown on vero cells. Keep medicine out of reach of children.
 Store below + 25°C. *Jauhi ubat dari kanak-kanak.* Controlled medicine.
Reconstituted vaccine must be used immediately. If not used immediately, it can be held for a period of maximum 6 hours, provided a syringe is used to cap the opening of the vial adapter and entire assembly is stored at 2 to 8°C.
FOR ORAL USE ONLY - NOT FOR INJECTION
 Reconstitute only with the diluent supplied by the manufacturer.
 This product contains substance(s) from animal origin (porcine and bovine).



Manufactured and released by: **MFG. LIC. NO.: 10**
SERUM INSTITUTE OF INDIA PVT. LTD.
 212/2, Hadapsar, Pune 411 028, INDIA

P. R. Holder:
SM Pharmaceuticals Sdn. Bhd.
 Lot 88, Sungai Petani Industrial Estate,
 08000, Sungai Petani, Kedah, Malaysia

MAL. No.:

B. NO:
 MFG.:
 EXP.:

Reason for issue: New		Specification: Self Adhesive Label To be printed on chromo art paper 80 gsm with release paper of 62 gsm supplied in roll form.		
Customer: Malaysia				
Product: Rotavirus Vaccine, Live Attenuated (Oral)	50 x 2.5 ml - 1 dose vials Store below + 25°C.	Colour: Pantone 220 C and Black		
Item Code number: 200XXXXX/0		Specification No.:		Artwork made to: 100%
Supercedes Item Code:			Dimensions: 100 x 90 mm	
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	MEDICAL DEPARTMENT	QUALITY ASSURANCE

File Name: E:\Packaging artworks as on 090212\Artworks SII Pvt Ltd 231015\Rotavirus\Malaysia\Rotavirus generic 25°C, 1 dose, Malaysia.cdr Date: 29.10.2021

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