



SERUM INSTITUTE OF INDIA PVT. LTD.

The change of product name by adding prefix SII to the generic name; there is no significant change in the proposed label as compared to the current label as SII Rubella Vaccine is already incorporated in the current label.

Sii	RUBELLA VACCINE, Live, Attenuated (Freeze-Dried)
Dose : 0.5 ml S/C	50 x 1 dose
Live, attenuated Rubella virus (<i>Wistar RA 27/3</i> Strain)	
Each dose contains	NOT LESS THAN
1000 CCID ₅₀ of Rubella virus	
Reconstitute with 0.5 ml diluent	
Use immediately after reconstitution	
Do not administer to a pregnant woman	
Store at 2 - 8°C	Keep medicine out of reach of children.
Protect from light	Jauhi ubat-ubatan daripada kanak-kanak
Controlled Medicine	Meets W.H.O. Requirements
Ubat terkawal	Reconstitute only with the diluent supplied by the manufacturer.
 Manufactured by:	MFG. LIC. NO. : 10
SERUM INSTITUTE OF INDIA PVT. LTD.	
212/2, 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 20033361AZ	
B. No.:	
MFG. :	
EXP. :	
20013973/0	

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: RUBELLA VACCINE, Live, Attenuated (Freeze-Dried)				
50 x 1 dose		Colour: Pantone 1605C and Black		
Item Code number: 20013973/0		Specification No.:		Artwork made to: 100%
Supersedes Item Code:			Dimensions: 100 x 90 mm	
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	MEDICAL DEPARTMENT	QUALITY ASSURANCE