



Corporate Plant Format

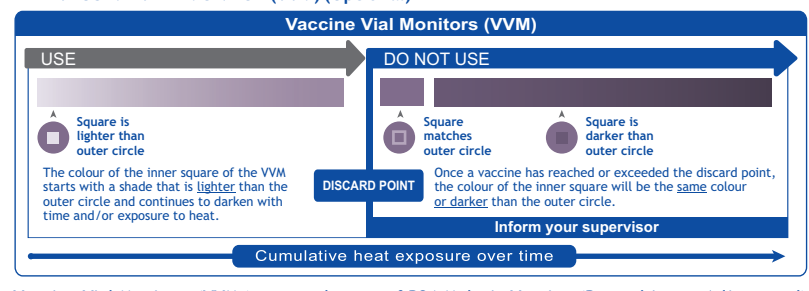
Table with 4 columns: Title, Format No., Effective Date, Page No. Values: Artwork Format, 2002-0001-F0003-000, 09/11/2020, 1 of 1

SII

R21 Malaria Vaccine (Recombinant, Adjuvanted)

1 NAME OF THE MEDICINAL PRODUCT
R21 Malaria Vaccine (Recombinant, Adjuvanted)
2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each dose of 0.5 mL contains
1,2 R21 Malaria Antigen: 5 mcg
3 Matrix-M1 (Adjuvant): 50 mcg
3 PHARMACEUTICAL FORM
Solution for injection
4 CLINICAL PARTICULARS
4.1 Therapeutic indications
4.2 Posology and method of administration
4.3 Contraindications
4.4 Special warnings and special precautions for use

4.9 Overdose
No case of overdose has been reported. In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.
5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
5.2 Pharmacokinetic properties
5.3 Preclinical safety data
6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
6.2 Incompatibilities
6.3 Shelf-life
6.4 Special precautions for storage
6.5 Nature and contents of container
6.6 Special Precautions for Disposal and Other Handling
THE VACCINE VIAL MONITOR (VVM) (Optional)
7 DATE OF REVISION OF THE TEXT: November 2023



Vaccine Vial Monitors (VVMs) are on the cap of R21 Malaria Vaccine (Recombinant, Adjuvanted) supplied through Serum Institute of India Pvt. Ltd. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed.

Table 1: Adverse reactions reported after 4 doses of the vaccine

Table with 3 columns: System Organ Class, Frequency, Adverse reactions. Rows include Metabolism and nutrition disorders, Psychiatric disorders, Nervous system disorders, Gastrointestinal disorders, and General disorders and administration site conditions.

Manufactured by: SERUM INSTITUTE OF INDIA PVT. LTD. 212/2, Hadapsar, Pune 411028, INDIA

20018852/0

Table with 5 columns: Reason for issue, Customer, Product, Item Code number, Specification No., Supercedes Item Code, Dimensions, PACKAGING DEVELOPMENT, QUALITY CONTROL, REGULATORY AFFAIRS, MEDICAL DEPARTMENT, QUALITY ASSURANCE