**R21 Malaria Vaccine (Recombinant, Adjuvanted)**

**Table of Contents**

1. NAME OF THE MEDICINAL PRODUCT
2. QUALITATIVE AND QUANTITATIVE CONTENT
3. PHARMACOLOGICAL GROUP
4. PHARMACOLOGICAL PROPERTIES
5. PHARMACODYNAMIC PROPERTIES
6. INDICATIONS
7. PREPARATION
8. CONTRAINDICATIONS
9. ADDITIONAL INFORMATION
10. ADVERSE REACTIONS
11. USE
12. POSOLOGY
13. PACKAGING AND STORING
14. SPECIAL INSTRUCTIONS FOR USE
15. OVERDOSE
16. SPECIAL INSTRUCTIONS FOR STORAGE
17. PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING
18. SPECIFICATION
19. MANUFACTURER

**1. NAME OF THE MEDICINAL PRODUCT**

R21 Malaria Vaccine (Recombinant, Adjuvanted)

**2. QUALITATIVE AND QUANTITATIVE CONTENT**

Each dose of 0.5 mL contains:

- **R21 Malaria Antigen:** 5 mcg
- **Matrix-M1 adjuvant:** 50 mcg

**3. PHARMACOLOGICAL GROUP**

Pharmacotherapeutic group: Parasitic vaccines, ATC code: J07XA

**4. PHARMACOLOGICAL PROPERTIES**

R21 Malaria Vaccine (Recombinant, Adjuvanted) is a pre-erythrocytic vaccine intended to protect against malaria caused by Plasmodium falciparum.

**5. PHARMACODYNAMIC PROPERTIES**

The vaccine is designed to protect against malaria by inducing an immune response that targets the sporozoite stage of the parasite. This results in a reduced ability of infected mosquitoes to transmit the disease.

**6. INDICATIONS**

R21 Malaria Vaccine (Recombinant, Adjuvanted) is indicated for the active immunisation of children and infants against malaria caused by Plasmodium falciparum. It is recommended for use in children aged above 24 months of age, if there is no sufficient bulk of muscle at deltoid site.

**7. PREPARATION**

The solution is clear, colourless to mildly turbid.

**8. CONTRAINDICATIONS**

There are no absolute contraindications for the use of R21 Malaria Vaccine (Recombinant, Adjuvanted).

**9. ADDITIONAL INFORMATION**

- **Use with prophylactic administration of antipyretics**: Not relevant.
- **Fertility, pregnancy and lactation**: The use of other malaria control measures recommended locally should not be interrupted.
- **Method of administration**: Three doses, each of 5 mcg R21 and 50 mcg Matrix-M1 should be given at monthly intervals.
- **Fourth dose**: A fourth dose is recommended 12 months after the third dose.

**10. ADVERSE REACTIONS**

Common adverse reactions include:

- Fever
- Loss of appetite
- Drowsiness
- Local injection site conditions

Uncommon adverse reactions include:

- Headache
- Influenza-like syndrome

**11. USE**

- **Use**: R21 Malaria Vaccine (Recombinant, Adjuvanted) is a pre-erythrocytic vaccine intended to protect against malaria caused by Plasmodium falciparum.
- **Dosage**: Three doses, each of 5 mcg R21 and 50 mcg Matrix-M1 should be given at monthly intervals.
- **Fifth dose**: The fifth dose is not recommended.

**12. POSOLOGY**

**13. PACKAGING AND STORING**

Store in a refrigerator (+2º to +8ºC). Once opened, multi-dose vials should be used as soon as practically possible and within six hours, whichever comes first.

**14. SPECIAL INSTRUCTIONS FOR USE**

- **Use**: Against malaria caused by Plasmodium species, except P. malariae.
- **Dosage**: Three doses, each of 5 mcg R21 and 50 mcg Matrix-M1 should be given at monthly intervals.
- **Fifth dose**: The fifth dose is not recommended.

**15. OVERDOSE**

No case of overdose has been reported. In the event of overdose, monitoring of vital signs and supportive measures may be required.

**16. SPECIAL INSTRUCTIONS FOR STORAGE**

Store in a refrigerator (+2º to +8ºC). Once opened, multi-dose vials should be used as soon as practically possible and within six hours, whichever comes first.

**17. PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING**

- **Disposal**: After opening of the medicinal product, see Section 6.3.
- **Store in an original package in order to protect from light.** For storage condition, after first opening, use the product within six hours, whichever comes first.

**18. SPECIFICATION**

**19. MANUFACTURER**

SERUM INSTITUTE OF INDIA PVT. LTD.

3, Hadapsar, Pune 411028, INDIA

**Reason for issue: New**

**Specification**: Printed on bible paper 40 gsm

**Product Code number**: 2001858200

**Supersedes Item Code**: Dimensions: 123 x 494 mm