Rotavirus Vaccine
( Live Attenuated, Oral), IP
VERO CELL DERIVED, IP

1. NAME AND DESCRIPTION OF THE ACTIVELY IMMUNIZING

Rotavirus Vaccine (Live Attenuated, Oral) is a live attenuated vaccine containing suspension of the attenuated strains of human rotavirus. The rotaviruses are classified in a dual classification system based on properties on the surface of the virus. The virus is double stranded, linear RNA virus within the Reoviridae family of the order Reovirales which are the etiologic agents of non-bacterial diarrhea in children. 

Rotavac 5D is a live attenuated oral vaccine containing the 5D strain of rotavirus (NL17/97) prepared using the technique of serial passage in Vero cells.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 mL contains:

- Kanamycin Acid Sulphate IP
- Dipotassium Phosphate IP
- Magnesium Hydroxide IP
- Sodium Bicarbonate IP
- Lactalbumin Hydrolysate (LAH)
- Human Albumin IP
- Sodium Citrate Dihydrate IP
- Sodium Chloride IP
- Water for Injections IP

3. PHARMACOLOGICAL FORM

Rotavac 5D is a yellow oral paste for oral use.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For prophylactic use only.

4.2. Preclinical and clinical trials and laboratory identification

4.3. Postmarketing and clinical trials

4.4. Dose and administration

4.5. Overdose

4.6. Adverse reactions

4.7. Pregnancy and lactation

4.8. Special precautions for use

4.9. Interactions

4.10. Effectiveness for infants up to 6 months

4.11. Effectiveness for infants 7-12 months

4.12. Incompatibilities

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

5.2. Pharmacokinetic properties

6. CLINICAL EFFICACY

6.1. Efficacy

6.2. Immunogenicity

6.3. Intussusception

6.4. Tolerability

7. PREPARATION

7.1. Pharmaceutical Formulations

7.2. Preclinical safety data

7.3. Clinical safety data

7.4. Administration of Rotavac Vaccine

7.5. Post-marketing surveillance

8. SPECIFICATION

8.1. Packaging

8.2. Mfg.

8.3. Shelf Life

8.4. Storing and Handling

9. ADMINISTRATION OF ROTAVAC VACCINE

10. FFP III Filtering Diagram

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Rotavac Vaccine (Live Attenuated, Oral, IP)

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