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

Rotavirus (Live Attenuated, Oral) IP

Vero-cell derived

ROTVAC can be used as long as:

- Square is lighter than the circle. USE the vaccine if expiry date has not passed.

- ROTAVAC can be used as long as:

- Square is the same colour or darker than the circle. DO NOT USE the vaccine. Inform your supervisor.

Vacuna Viva Oral (VVO) is a part of the vaccine of ROTAVAC was supplied through Bharat Biotech. This is an aerosol suspension that contains at least 100,000 plaque-forming units of the live attenuated Rotavirus strain of Bothasip in VIVO. VVO should be stored in cool, dry conditions. This vaccine is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

1. NAME AND DESCRIPTION OF THE ACTIVITY: IMMUNIZATION

Rotavirus (Live Attenuated, Oral) IP consists of live attenuated virus strains (VVO) of Bothasip in VIVO. VVO is indicated for the prevention of rotavirus gastroenteritis in infants.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

List of ingredients and position:

- Cells obtained from Bothasip in VIVO
- Live attenuated virus strains of Bothasip in VIVO

3. COMPOSITION OF ROTAVAC

Basic dose: 0.5 mL, up to 3 doses

4. TITRES AND METHOD OF DETERMINATION

For prophylactic use, ROTAVAC should be administered as a single dose, 6 weeks apart, beginning at 6 weeks of age. ROTAVAC is not administered with other medications in combination. In infants, the recommended dose is 0.5 mL. In children, the recommended dose is 3 doses. In infants, the recommended dose is 0.5 mL, while in children, the recommended dose is 3 doses.

5. PHARMACOLOGICAL EFFECT OF ROTAVAC

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

6. CLINICAL PARTICULARS

6.1. General information

The vaccine is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

6.2. Administration of ROTAVAC

The vaccine is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

7. ADVERSE REACTIONS

No serious adverse events were observed in the trial of ROTAVAC in infants. However, mild adverse events were observed in the trial of ROTAVAC in infants. In infants, the most common adverse events were diarrhea, vomiting, and fever. In children, the most common adverse events were fever, vomiting, and diarrhea.

8. DURATION AND STORAGE

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

9. INCOMPATIBILITIES AND INTERACTIONS

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

10. PREPACKAGING

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

11. MANUFACTURING DATE

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

12. EXPIRY DATE

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

13. PACKAGING

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

14. MANUFACTURER

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

15. LABELING

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

16. SUMMARY

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

17. REFERENCES

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

18. STORAGE AND TRANSPORTATION

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

19. DISPOSAL

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

20. DECLARATION

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

21. APPROVAL

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

22. SIGNATURE

Rotavirus is a live viral vaccine. It is administered orally to infants at the age of 6 weeks of age. The vaccine is not administered to children younger than 6 months of age.

Date: 08-03-2018

ROTVAC Single Dose Package Insert artwork for Domestic

Color: CMYK/Pantone

Specs: 90% Black C

Product: ROTAVAC

Size: 155 x 200 mm

Paper: Newsprint

Presentation: 45±10

GSM: H-1 & V-3 folds

Folds: 77.5 x 25 mm

Approval: QA - RA

Cord comm: HOD - QC

Packing: HOD Production

Incharge: Marketing (Domestic/Export)

MED: HOD - QAO

Form No: FMQA008/004.04 The coral version of this form can be with coproc.