

# ROTAVAC - new rotavirus vaccine

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***Source:** Bharat Biotech & the Live mint*

Bharat Biotech International launched a new variant of its rotavirus vaccine, Rotavac 5D, a smaller dosage form of its earlier oral immunization shot that can be stored at a relatively higher temperature. The original Rotavac was made part of the Indian immunization program in 2016 after it received regulatory approval in 2014.

## **What is it?**

Rotavirus Vaccine (Live Attenuated, Oral) is a **monovalent liquid frozen vaccine containing live rotavirus 116E** strain prepared in Vero cells for the prevention of rotavirus gastroenteritis.

## **Usage conditions**

- ROTAVAC should be administered as a 3-dose regimen, 4 weeks apart, beginning at 6 weeks of age and should not be administered to children older than 8 months of age.
- ROTAVAC has a **shelf life of 5 years** when stored at -20°C till the expiry date and can be stored for up to six months between 5°C ±3°C.

## **Other key highlights**

- Rotavac received WHO-Prequalification in January 2018.
- Rotavirus 116E is isolated from asymptomatic neonates in 1986-88 at the All India Institute of Medical Sciences, New Delhi.
- ROTAVAC **was developed as a Social Innovation Project under a public-private partnership** involving highly-regarded national and international organizations.

- **The multicenter phase3 efficacy and safety clinical trial on ROTAVAC was India's first and largest efficacy clinical trial on vaccines.**
- It was successfully completed in September 2013 after a 2-year follow up of infants.

## **Bharat Biotech**

- Bharat Biotech is an Indian biotechnology company, headquartered in Hyderabad, India.
- Bharat Biotech started operations in 1996
- Bharat Biotech is a pioneering biotechnology company known for its world-class R&D and manufacturing capabilities.
- Bharat Biotech has one of the largest pharmaceutical manufacturing plants of its kind in Asia-Pacific.
- It is the first bio-pharma facility in the country to be audited and approved by the Korean Food & Drugs Administration (KFDA) at Genome Valley, Hyderabad
- The company has around 60-70% market share for rotavirus vaccines in India.