

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 $5^{\circ}\text{C} \pm 3^{\circ}\text{C}$.

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.