



COVAXIN® for Children: India approves COVAXIN® in Children 6-12 years

- COVAXIN® is the one of the first COVID-19 vaccines in the world to generate data in 2-18 year age group.
- COVAXIN® was earlier approved for children 12-18 years of age.
- Whole-Virion inactivated SARS-CoV-2 Vaccine (BBV152) has proven to be safe, well-tolerated, and immunogenic in paediatric subjects in phase II/III study in children 2-18 years of age.
- Neutralizing antibodies in children on were 1.7 times higher than in adults.
- No serious adverse event was reported. Pain at the injection site was the most commonly reported adverse event. No cases of myocarditis or blood clots were reported, as is to be expected with inactivated vaccines.
- COVAXIN® exhibits robust immune responses in children with 2 doses and 6 months follow up, indicating durability of immune responses. Data was presented to the CDSCO Subject Expert Committee and will be published in the weeks to come.

Hyderabad, April 26, 2022: Bharat Biotech International Limited (BBIL), a global leader in vaccine innovation and developer of vaccines for infectious diseases, today announced that BBV152 (COVAXIN®), its whole-virion inactivated COVID-19 vaccine candidate, has received emergency use approval in children 6-12 years of age.

Bharat Biotech had conducted phase II/III, open-label, and multicenter studies to evaluate the safety, reactogenicity, and immunogenicity COVAXIN® in healthy children and adolescents in the 2-18 age group. The clinical trials conducted in the paediatric population between June 2021 to September 2021 have shown robust safety, reactogenicity, and immunogenicity. The data readouts were submitted to the Central Drugs Standard Control Organisation (CDSCO) during October 2021, and received emergency use nod for children aged 12-18 from DCGI during December 2021.

Dr. Krishna Ella, Chairman and Managing Director, Bharat Biotech, said, “We have established COVAXIN® as an universal vaccine for adults and children. Safety of the vaccine is critical for children and we are glad to share that COVAXIN® has now proven data for safety and immunogenicity in children. We have achieved our goal of developing a safe and efficacious COVID-19 vaccine for adults and children.”

Clinical trials in children documented seroconversion at 95-98%, four weeks after the second dose, indicating superior antibody responses in children when compared to adults and also displayed Th1 bias. In earlier COVAXIN® studies in adults, cross reactive memory T cells against all variants of concern was reported. Data from neutralization studies against Delta and Omicron variants have been published along with impact of cell mediated immune responses. Since COVAXIN®, is an inactivated vaccine corroborative results are expected in children similar to that of adults.

Booster dose of COVAXIN® in adults, generated robust neutralizing antibody responses against both Omicron (B.1.529) and Delta (B.1.617.2) using a live virus neutralization assay. 100% of test serum samples showed neutralization of the Delta variant and more than 90% of serum samples showed neutralization of the Omicron variant. These data add to the body of evidence that the broad-spectrum mechanism of action of a whole virus inactivated COVID-19 vaccine, like COVAXIN® (BBV152), is a viable option in this continuously evolving pandemic

COVAXIN® is formulated uniquely such that the same dosage can be administered to adults and children alike. COVAXIN® is a ready-to-use a liquid vaccine, stored at 2-8°C, with 12 months shelf life and multi-dose vial policy. The same vaccine can also be used for 2 dose primary immunization and for booster dose vaccinations, making it truly an universal vaccine.

Fresh stocks of COVAXIN® are available and ready for supplies. Bharat Biotech has readily available more than 50 million doses of COVAXIN in vials, and more than 200 million doses as drug substance. Additional production capacity is also available to meet product demand.

<https://www.bharatbiotech.com/covaxin.html>



About Bharat Biotech

Bharat Biotech has established an excellent track record of innovation with more than 145 global patents, a wide product portfolio of more than 16 vaccines, 4 bio-therapeutics, registrations in more than 123 countries, and the World Health Organization (WHO) Pre-qualifications. Located in Genome Valley in Hyderabad, India, a hub for the global biotech industry, Bharat Biotech has built a world-class vaccine & bio-therapeutics, research & product development, Bio-Safety Level 3 manufacturing, and vaccine supply and distribution. Having delivered more than 4 billion doses of vaccines worldwide, Bharat Biotech continues to lead innovation and has developed vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis (JENVAC®), Rabies, Chikungunya, Zika, Cholera, and the world's first tetanus toxoid conjugated vaccine for Typhoid. Bharat's commitment to global social innovation programs and the public-private partnership resulted in introducing path-breaking WHO pre-qualified vaccines BIOPOLIO®, ROTAVAC®, ROTAVAC® 5D, and Typbar TCV® combatting polio, rotavirus, typhoid infections, respectively. The acquisition of Chiron Behring Vaccines has positioned Bharat Biotech as the world's largest rabies vaccine manufacturer with Chirorab® and Indirab®.

More about COVAXIN® - <https://www.bharatbiotech.com/covaxin.html>

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