

Gennova BioPharma launches small pack size of HAMSYL drug for paediatric cancer care

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India's first-ever 1500 IU paediatric pack size reshaping paediatric oncology care

Pune-based Gennova Biopharmaceuticals has announced the launch of India's first paediatric pack size of pegaspargase, HAMSYL – Junior, which will now be available in a 1500 IU pack size.

This marks a significant milestone in advancing healthcare for Indian children suffering from an orphan disease called *Acute Lymphoblastic Leukaemia* (ALL), a rare and challenging form of blood cancer primarily affecting children.

Gennova's commitment to addressing ALL began in 2014 with the introduction of HAMSYL, an affordable and quality-assured pegaspargase available in 3750 IU pack size. Notably, this product supported access to the needs of patients against a time-consuming and cumbersome process of importing the drug and reduced the cost of the then-available standard of care in terms of drug pricing, in the fight against ALL.

Initially approved for the second-line treatment of ALL, HAMSYL received recognition for its safety and efficacy in real-world patients. This paved the way for its approval as a first-line therapy in 2019, a testament to its demonstrated bioequivalence with the innovator molecule.

Following the HAMSYL launch, Gennova's engagement with Key Opinion Leaders in paediatric haematology revealed the need for a different pack size specifically made for children. In response, Gennova introduced HAMSYL Junior, involving subsequent new drug applications with CDSCO, New Delhi, to modify the pack size. This will not only suit the smaller body size but also prevent wastage.

With a 1500 IU pack size and a 2 mL fill volume, HAMSYL Junior ensures optimal dosing while retaining the same API

strength (750 IU/mL), marking a significant stride in providing paediatric patients in India with a specifically designed and accessible treatment.