Gennova Biopharmaceuticals

Oncology

Pegaspargase

HAMSYL®

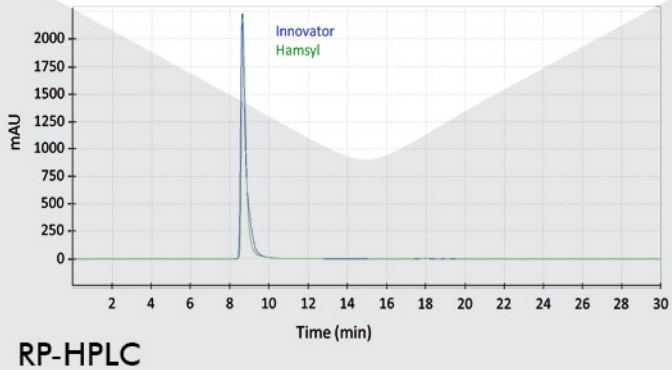
Indicated as a component of multi agent chemotherapeutic regimen for the treatment of patients with Acute Lymphoblastic Leukemia who are hypersensitive to L-asparaginase

5 Years

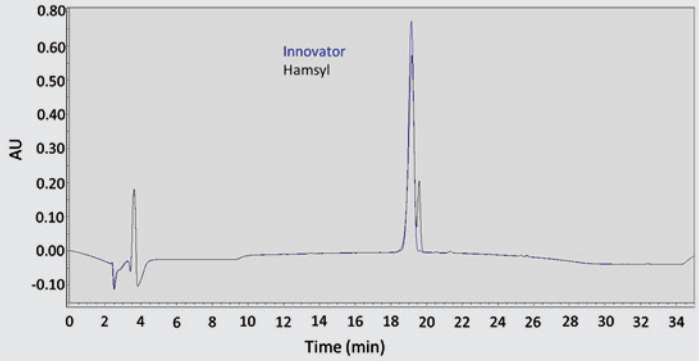
Hamsyl®, comparison with the Innovator's product

The retention time and peak profile of Gennova's product, Hamsyl®, matches with that of the Innovator's product. This is only possible if there is a match of size and purity of both the products. SEC-HPLC analysis shows Hamsyl® is 99.9% pure, matching Innovator's product. The single peak as observed for Hamsyl® by RP-HPLC indicates the presence of singular species. The retention time of Gennova's product, Hamsyl®, matches with that of the Innovator's as determined by RP-HPLC.

SEC-HPLC

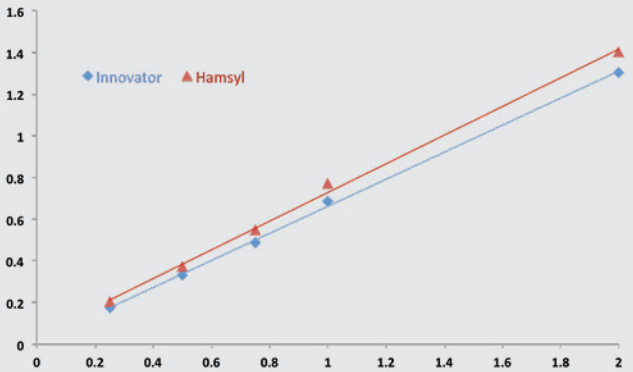


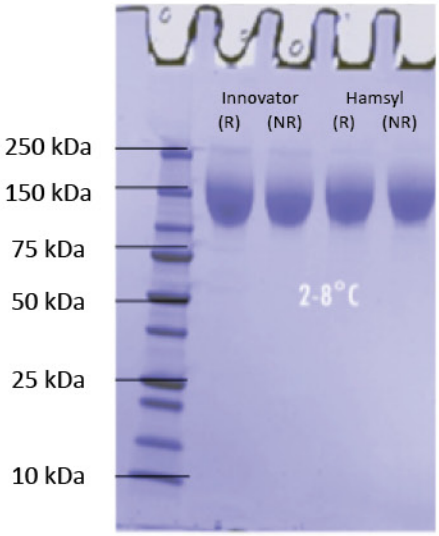
RP-HPLC



Hamsyl® is comparable in homogeneity and purity with the Innovator's product

In vitro activity assay shows both Gennova's Hamsyl® and Innovator's product having similar colorimetric output [corresponding to ammonia release] at various dilutions.





Human Clinical Study

A prospective, open label, randomized, active control, parallel design, comparative PK study of IM Hamsyl® versus Oncaspar® in pediatric patients with relapsed cases of ALL

Hamsyl® is bioequivalent to Innovator in this study.

Trough asparaginase level of >100 IU/L with Hamsyl® at 1000 IU/m² observed to be comparable with Innovator's product.

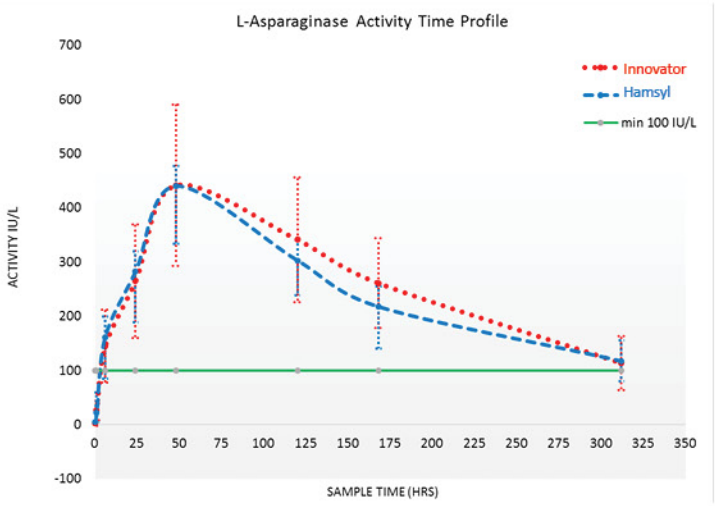
Overall survival rate of Pegaspargase treatment in relapsed cases of ALL >70% at 2 year.

Hamsyl® was well tolerated and found to be safe and efficacious in the relapsed patients of ALL.

Gennova launched Hamsyl® (generic Pegaspargase Injection) in 2014

Hamsyl® is produced from pegylation of native L-Asparaginase

Approved for to be used in Acute Lymphoblastic Leukaemia (ALL) patients with hypersensitivity to L-asparaginase



1st generic pegaspargase, launched at 1/3rd of the Innovator's price

Till date >3,000 Patients of ALL have benefitted, 6 mandatory Periodic safety reports submitted to the DCG(I)

PEDIATRIC HEMATOLOGY AND ONCOLOGY
https://doi.org/10.1080/08880018.2018.1538277
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Experience with generic pegylated L-asparaginase in children with acute lymphoblastic leukemia and monitoring of serum asparaginase activity

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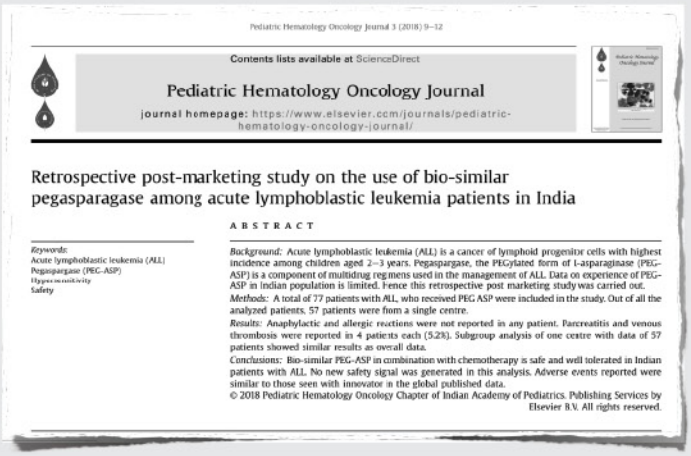
It was concluded that use of generic P-Asp (Hamsyl®) was associated with adequate trough levels and it was well tolerated in our population of patients.



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Retrospective post-marketing study on the use of bio-similar pegasparagase among acute lymphoblastic leukemia patients in India

ABSTRACT

Keywords:
Acute lymphoblastic leukemia (ALL)
Pegasparagase (PEG-ASP)
Hypersensitivity
Safety

Background: Acute lymphoblastic leukemia (ALL) is a cancer of lymphoid progenitor cells with highest incidence among children aged 2–3 years. Pegaspargase, the PEGylated form of L-asparaginase (PEG-ASP) is a component of multidrug regimens used in the management of ALL. Data on experience of PEG-ASP in Indian population is limited. Hence this retrospective post marketing study was carried out.

Methods: A total of 77 patients with ALL, who received PEG ASP were included in the study. Out of all the analyzed patients, 57 patients were from a single centre.

Results: Anaphylactic and allergic reactions were not reported in any patient. Pancreatitis and venous thrombosis were reported in 4 patients each (5.2%). Subgroup analysis of one centre with data of 57 patients showed similar results as overall data.

Conclusions: Bio-similar PEG-ASP in combination with chemotherapy is safe and well tolerated in Indian patients with ALL. No new safety signal was generated in this analysis. Adverse events reported were similar to those seen with innovator in the global published data.

PEG ASP (Hamsyl®) in combination with chemotherapy appears to be safe and well tolerated as found in this post marketing survey.

No new safety signal was generated in this analysis with bio-similar PEG ASP. Adverse events reported were similar to those seen with innovator in the global published data.

Gennova Biopharmaceuticals Ltd., headquartered in Pune, India, is a biotechnology company dedicated to the development, production and commercialization of bio-therapeutics to address life-threatening diseases across various indications. Incorporating recombinant DNA technologies together with innovative bio-manufacturing practices, Gennova has created cost effective solutions for manufacturing and successfully commercializing bio-therapeutics across cardiovascular, neurology, nephrology and oncology markets.

Gennova Biopharmaceuticals

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