

Adagen® (pegademase bovine) – Product discontinuation

- On January 18, 2019, the <u>FDA announced</u> the discontinuation of Leadiant Biosciences' <u>Adagen</u> (pegademase bovine) 375 units/1.5 mL injection.
 - The discontinuation of the manufacture of Adagen is due to the permanent shortage of the active ingredient.
 - The discontinuation of the product is not due to product quality, safety, or efficacy concerns.
 - Based on the demand in mid-January 2019, the inventory is estimated to runout by late-March 2019.
- Adagen is approved for enzyme replacement therapy for adenosine deaminase deficiency in patients with severe combined immunodeficiency disease who are not suitable candidates for – or who have failed – bone marrow transplantation.



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