

Apidra® (*insulin glulisine*)

Pharmacology

Insulin glulisine (rDNA origin) is a short-acting recombinant human insulin analogue, differing from regular human insulin because of its rapid onset and shorter duration of action.¹ Because it works so quickly, it can be injected within 15 minutes before or 20 minutes after starting a meal, giving patients flexibility regarding administration time.¹

Pharmacokinetics/Pharmacodynamics

- Insulin glulisine vs. regular human insulin (RHI)¹:
 - IV administration: equipotent insulin lowering activity
 - SC administration: insulin glulisine is more rapid-acting and has a shorter duration of action
 - Insulin glulisine is absorbed up to two times faster and can reach peak concentrations up to approximately two times higher than RHI
- The absolute bioavailability of insulin glulisine after SC administration is about 70% (abdomen 73%, deltoid 71%, thigh 68%)¹

Administration

- Insulin glulisine should be injected within 15 minutes before or 20 minutes after starting a meal.¹
- Insulin glulisine should be used in regimens with a longer-acting insulin or a basal insulin analogue and can be used with oral hypoglycemic agents.¹
- Insulin glulisine may be used for Continuous Subcutaneous Insulin Infusion (CSII) in pump systems but should not be mixed or diluted with anything else.¹
- Insulin glulisine can be mixed with NPH human insulin but mixtures must be injected immediately and should not be given intravenously.¹
- Neither Apidra cartridges nor Apidra SoloSTAR can be mixed.¹

Efficacy

- Study “3001” (insulin glulisine [Apidra®] vs. insulin lispro [Humalog®] in Type 1 diabetes): Results found no statistically significant difference between the treatment groups in terms of mean change in HbA1c from baseline to endpoint of the study.²
- Meta-analysis 1 (efficacy of insulin glulisine vs. regular human insulin in Type 2 diabetes) and Meta-analysis 2 (efficacy of insulin lispro vs. regular human insulin in Type 2 diabetes) found similar results to “Study 3001.”²
- There was no statistically significant difference between the Meta-analysis 1 and Meta-analysis 2 results regarding the mean change in HbA1c from baseline to endpoint, which was cited as evidence of the equivalence of insulin glulisine and insulin lispro in Type II diabetes.²

Strength/Form	Price (\$/15mL) ^{3,4}	Formulary	EDS Criteria ³
100 U/mL INJECTION SOLUTION (10mL Vial)	\$48	Yes (EDS)	(a) For treatment of Type 1 diabetes. (b) For treatment of difficult to control Type 2 diabetes in patients who have not responded to alternative insulin agents listed in the Formulary.
100 U/mL PRE-FILLED PEN (5X3 mL) (Apidra SoloSTAR)	\$62	Yes (EDS)	
100 U/mL INJECTION SOLUTION (3mL Cartridge)	\$64	No	N/A

*EDS criteria is the same for all rapid-acting insulins (insulin lispro, insulin aspart, and insulin glulisine)³

References

1. Sanofi-aventis Canada Inc. Apidra (Product Monograph). February 15, 2010. <<http://www.sanofi-aventis.ca/products/en/apidra.pdf>>
2. Commonwealth of Australia. Insulin Glulisine (Clinical Trials). June 29, 2007. <<http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-psd-insulin-glulisine-mar07>>
3. Government of Saskatchewan. Drug Plan and Extended Benefits Branch (Online Formulary: Apidra). February 1, 2010. <<http://formulary.drugplan.health.gov.sk.ca/>>
4. McKesson Canada. PharmaClik: Apidra. Saint-Laurent, QB; c2005. Accessed March 15, 2010. <<http://clients.mckesson.ca>>