

## Rapid-acting insulin quick guide<sup>a,b</sup>

	Insulin lispro			Insulin lispro-aabc	Insulin aspart			Insulin glulisine
	Humalog	Unbranded	Admelog	Lyumjev	Novolog	Unbranded	Fiasp	Apidra
<b>Manufacturer</b>	Eli Lilly	Eli Lilly	Sanofi	Eli Lilly	Novo Nordisk	Novo Nordisk	Novo Nordisk	Sanofi
<b>Approval / Launch date</b>	1996	2019 <sup>1</sup>	2017	2020	2000	2020 <sup>2</sup>	2017	2004
<b>Description</b>	Brand	Unbranded biologic	Brand copy	Brand	Brand	Unbranded biologic	Brand	Brand
<b>Approval pathway<sup>3</sup> Purple Book</b>	351(a) / BLA*  <i>*previously approved under 505(b)(1) pathway and converted to BLA in 2020</i>	NA – authorized	351(a) / BLA*  <i>*previously approved under 505(b)(2) pathway and converted to BLA in 2020</i>	351(a) / BLA	351(a) / BLA*  <i>*previously approved under 505(b)(1) pathway and converted to BLA in 2020</i>	NA – authorized	351(a) / BLA*  <i>*previously approved under 505(b)(1) pathway and converted to BLA in 2020</i>	351(a) / BLA*  <i>*previously approved under 505(b)(1) pathway and converted to BLA in 2020</i>
<b>Reference product</b>	Yes	No	Yes	Yes	Yes	No	Yes	Yes
<b>Interchangeable<sup>4</sup></b>	Yes (with unbranded insulin lispro only)	Yes (with Humalog only)	No	No	Yes (with unbranded insulin aspart only)	Yes (with Novolog only)	No	NA
<b>Indication</b>	Improved glycemic control in adult and pediatric patients with diabetes mellitus							
<b>Dosage and administration</b>								
<b>Dosage</b>	Dosage of rapid-acting insulins products must be individualized based on the route of administration and patient-specific factors, such as metabolic needs, blood glucose monitoring results, and glycemic control goal.							
<b>Routes of administration</b>	<ul style="list-style-type: none"> <li>• Subcutaneous injection</li> <li>• Insulin pump</li> <li>• IV</li> </ul> <p>Refer to product labeling for information on preparation</p>							
<b>Timing of dose (for subcutaneous injections)</b>	Within 15 min before a meal or immediately following a meal			At start of a meal or within 20 min following a meal	Within 5-10 min before a meal		At start of a meal or within 20 min following a meal	Within 15 before a meal or within 20 min after a meal
<b>Onset (for subcutaneous injection)<sup>5</sup></b>	~30-45 min		Similar to Humalog	~15-32 min	~20-30 min		~16-22 min	~12-30 min
<b>Peak effect (for subcutaneous injection)<sup>5</sup></b>	2.5-3 h		~2 h	~2-3 h	~1-3 h		~1.5-2.5 h	~2-3 h

	Insulin lispro			Insulin lispro-aabc	Insulin aspart			Insulin glulisine
	Humalog	Unbranded	Admelog	Lyumjev	Novolog	Unbranded	Fiasp	Apidra
<b>Duration</b> (for subcutaneous injection) <sup>5</sup>	~6-7 h		~7 h	~5-7 h	~3-7 h		~5-7 h	~3-4 h
<b>Mixing with other insulins</b>	<ul style="list-style-type: none"> <li>Humalog U-100 may be mixed with NPH insulin only for subcutaneous injection</li> <li>Do not mix with other insulins when using via insulin pump</li> <li>Humalog U-200 may not be mixed with any other insulin products</li> </ul>	<ul style="list-style-type: none"> <li>Unbranded insulin lispro 100 unit/mL may be mixed with NPH insulin only for subcutaneous injection</li> <li>Do not mix with other insulins when using via insulin pump</li> </ul>	<ul style="list-style-type: none"> <li>Do not mix with any other insulin products.</li> </ul>	<ul style="list-style-type: none"> <li>Do not mix with any other insulin products.</li> </ul>	<ul style="list-style-type: none"> <li>Novolog may be mixed with NPH insulin only for subcutaneous injection</li> <li>Do not mix with other insulins when using via insulin pump</li> </ul>	<ul style="list-style-type: none"> <li>Unbranded insulin aspart may be mixed with NPH insulin only for subcutaneous injection</li> <li>Do not mix with other insulins when using via insulin pump</li> </ul>	<ul style="list-style-type: none"> <li>Do not mix with any other insulin products.</li> </ul>	<ul style="list-style-type: none"> <li>Apidra may be mixed with NPH insulin only for subcutaneous injection</li> <li>Do not mix with other insulins when using via insulin pump</li> </ul>
<b>Product composition (per mL)</b>								
100 unit/mL concentration	<ul style="list-style-type: none"> <li>Insulin lispro 100 units</li> <li>Dibasic sodium phosphate 1 mg</li> <li>Glycerin 16 mg</li> <li>Metacresol 3.15 mg</li> <li>Trace phenol</li> <li>Trace zinc oxide</li> <li>Water for injection</li> </ul>	<ul style="list-style-type: none"> <li>Insulin lispro 100 units</li> <li>Dibasic sodium phosphate 1.88 mg</li> <li>Glycerin 16 mg</li> <li>Metacresol 3.15 mg</li> <li>Trace zinc oxide</li> <li>Water for injection</li> </ul>	<ul style="list-style-type: none"> <li>Insulin lispro-aabc 100 units</li> <li>Glycerol 12.1 mg</li> <li>Magnesium chloride hexahydrate 1.02 mg</li> <li>Metacresol 3.15 mg</li> <li>Sodium citrate dihydrate 4.41 mg</li> <li>Treprostinil sodium 1.06 mcg</li> <li>Trace zinc oxide</li> <li>Water for injection</li> </ul>	<ul style="list-style-type: none"> <li>Insulin aspart 100 units</li> <li>Disodium hydrogen phosphate dihydrate 1.25 mg</li> <li>Glycerin 16 mg</li> <li>Metacresol 1.72 mg</li> <li>Phenol 1.5 mg</li> <li>Sodium chloride 0.58 mg</li> <li>Trace zinc</li> <li>Water for injection</li> </ul>	<ul style="list-style-type: none"> <li>Insulin aspart 100 units</li> <li>Arginine 3.48 mg</li> <li>Dibasic sodium phosphate 0.42 mg</li> <li>Glycerin 3.3 mg</li> <li>Metacresol 1.72 mg</li> <li>Niacinamide 20.8 mg</li> <li>Phenol 1.5 mg</li> <li>Trace zinc</li> <li>Water for injection</li> </ul>	<ul style="list-style-type: none"> <li>Insulin glulisine 100 units</li> <li>Metacresol 3.15 mg</li> <li>Polysorbate 20 0.01 mg</li> <li>Sodium chloride 5 mg</li> <li>Tromethamine 6 mg</li> <li>Water for injection</li> </ul>		
200 unit/mL concentration	<ul style="list-style-type: none"> <li>Insulin lispro 200 units</li> <li>Glycerin 16 mg</li> <li>Metacresol 3.15 mg</li> <li>Trace phenol</li> <li>Tromethamine 5 mg</li> <li>Trace zinc oxide</li> <li>Water for injection</li> </ul>	NA	<ul style="list-style-type: none"> <li>Insulin lispro-aabc 200 units</li> <li>Glycerol 12.1 mg</li> <li>Magnesium chloride hexahydrate 1.02 mg</li> </ul>	NA	NA	NA		

	Insulin lispro			Insulin lispro-aabc	Insulin aspart			Insulin glulisine
	Humalog	Unbranded	Admelog	Lyumjev	Novolog	Unbranded	Fiasp	Apidra
				<ul style="list-style-type: none"> <li>• Metacresol 3.15 mg</li> <li>• Sodium citrate dihydrate 4.41 mg</li> <li>• Treprostinil sodium 1.06 mcg</li> <li>• Trace zinc oxide</li> <li>• Water for injection</li> </ul>				
<b>How supplied</b>								
<b>100 unit/mL concentration</b>								
10 mL MDV	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3 mL MDV	<i>Discontinued<sup>f</sup></i>	No	Yes	No	No	No	No	No
3 mL prefilled pen, single-patient use	Yes (Kwikpen, Tempo Pen, Junior Kwikpen)	Yes (Kwikpen, Junior Kwikpen)	Yes (SoloStar)	Yes (Kwikpen, Tempo Pen, Junior Kwikpen)	Yes (FlexPen, FlexTouch)	Yes (FlexPen)	Yes (FlexTouch)	Yes (SoloStar)
3 mL single-patient use cartridges	Yes	No	No	Yes	Yes (PenFill)	Yes (PenFill)	Yes (PenFill)	No
1.6 mL single-patient use cartridges	No	No	No	No	No	No	Yes (PumpCart)	No
<b>200 unit/mL concentration</b>								
3 mL prefilled pen, single-patient use	Yes (Kwikpen)	No	No	Yes (Kwikpen)	No	No	No	No
<b>Storage</b>								
Unopened MDV and prefilled pens	<ul style="list-style-type: none"> <li>• Room temperature (up to 30°C): 28 d</li> <li>• Refrigerated (2° to 8°C): until expiration date</li> </ul>							
Unopened cartridge	<ul style="list-style-type: none"> <li>• Room temperature (up to 30°C): 28 d</li> <li>• Refrigerated (2° to 8°C) until expiration date</li> </ul>	NA	NA	<ul style="list-style-type: none"> <li>• Room temperature (up to 30°C): 28 d</li> <li>• Refrigerated (2° to 8°C): until expiration date</li> </ul>			<b>3 mL PenFill</b> <ul style="list-style-type: none"> <li>• Room temperature (up to 30°C): 28 d</li> <li>• Refrigerated (2° to 8°C): until expiration date</li> </ul> <b>1.6 mL PumpCart</b>	NA

	Insulin lispro			Insulin lispro-aabc	Insulin aspart			Insulin glulisine	
	Humalog	Unbranded	Admelog	Lyumjev	Novolog	Unbranded	Fiasp	Apidra	
							<ul style="list-style-type: none"> <li>Room temperature (up to 30°C): 18 d</li> <li>Refrigerated (2° to 8°C): until expiration date</li> </ul>		
In-use MDV	<ul style="list-style-type: none"> <li>Room temperature (up to 30°C): 28 d</li> <li>Refrigerated (2° to 8°C): 28 d</li> </ul>								
In-use prefilled pens	<ul style="list-style-type: none"> <li>Room temperature (up to 30°C): 28 d</li> <li>Do <u>not</u> refrigerate</li> </ul>						<ul style="list-style-type: none"> <li>Room temperature (up to 30°C): 28 d</li> <li>Refrigerated (2° to 8°C): 28 d</li> </ul>		
Use in insulin pump	Change reservoir at least every 7 d			Change reservoir at least every 9 d	Change reservoir at least every 7 d			<ul style="list-style-type: none"> <li>Change reservoir at least every 6 d</li> <li>Replace PumpCart cartridge at least every 4 d</li> </ul>	Change reservoir at least every 48 h
Admixture for IV administration	<ul style="list-style-type: none"> <li>Store refrigerated for up to 48 h</li> <li>IV bags may be used at room temperature for up to an additional 48 h</li> </ul>		<ul style="list-style-type: none"> <li>Store refrigerated for up to 24 h</li> <li>IV bags may be used at room temperature for up to 4 h</li> </ul>	<ul style="list-style-type: none"> <li>Store refrigerated for up to 4 d</li> <li>IV bags may be stored at room temperature for up to 12 h</li> </ul>	IV bags may be stored at room temperature for up to 24 h			IV bags may be stored at room temperature for up to 48 h	
<b>HCPCS codes</b> (current as of April 15, 2024) <sup>6</sup>									
Injection per 5 units	J1815			<b>J1814</b>	J1815		<b>J1812</b>	J1815	
Administration through insulin pump per 50 units	J1817			<b>J1813</b>	J1817		<b>J1811</b>	J1817	
<b>Status indicator</b> (current as of April 15, 2024) <sup>6</sup>									
Injection per 5 units	N								
Administration through insulin pump per 50 units	N	N	N	<b>K</b>	N	N	<b>K</b>	N	
<b>WAC</b> <sup>7</sup> (current as of April 15, 2024)	<ul style="list-style-type: none"> <li>10 mL MDV: \$66.40</li> </ul>	<ul style="list-style-type: none"> <li>10 mL MDV: \$25</li> <li>3 mL prefilled pen: \$31.82</li> </ul>	<ul style="list-style-type: none"> <li>10 mL MDV: \$98.07</li> </ul>	<ul style="list-style-type: none"> <li>10 mL MDV: \$274.70</li> </ul>	<ul style="list-style-type: none"> <li>10 mL MDV: \$72.34</li> </ul>	<ul style="list-style-type: none"> <li>10 mL MDV: \$72.34</li> </ul>	<ul style="list-style-type: none"> <li>10 mL MDV: \$289.36</li> </ul>	<ul style="list-style-type: none"> <li>10 mL MDV: \$85.19</li> </ul>	

	Insulin lispro			Insulin lispro-aabc	Insulin aspart			Insulin glulisine
	Humalog	Unbranded	Admelog	Lyumjev	Novolog	Unbranded	Fiasp	Apidra
	<ul style="list-style-type: none"> <li>• 3 mL prefilled pen (100 unit/mL): \$31.82</li> <li>• 3 mL prefilled pen (200 unit/mL): \$212.16</li> <li>• 3 mL single-patient use cartridges: \$30.63</li> </ul>		<ul style="list-style-type: none"> <li>• 3 mL MDV: \$39.23</li> <li>• 3 mL prefilled pen: \$37.87</li> </ul>	<ul style="list-style-type: none"> <li>• 3 mL prefilled pen (100 unit/mL): \$106.08</li> <li>• 3 mL prefilled pen (200 unit/mL): \$212.16</li> </ul>	<ul style="list-style-type: none"> <li>• 3 mL prefilled pen: \$139.71</li> <li>• 3 mL single-patient use cartridges: \$26.87</li> </ul>	<ul style="list-style-type: none"> <li>• 3 mL prefilled pen: \$27.94</li> <li>• 3 mL single-patient use cartridges: \$26.87</li> </ul>	<ul style="list-style-type: none"> <li>• 3 mL prefilled pen: \$111.77</li> <li>• 3 mL single-patient use cartridges: \$107.49</li> <li>• 1.6 mL single-patient use cartridges: \$57.33</li> </ul>	<ul style="list-style-type: none"> <li>• 3 mL prefilled pen: \$32.91</li> </ul>
<b>Vizient contract</b>	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes

<sup>a</sup> Unless otherwise noted, product information retrieved from respective product prescribing information and the Food and Drug Administration website available at Drugs@FDA, accessed April 2024.

<sup>b</sup> There are currently no biosimilar rapid-acting insulin products approved in the US. However, a biosimilar version of insulin lispro and insulin aspart from Gan & Lee / Sandoz are both seeking approval from FDA with a possible decision in April 2024. These products may seek interchangeability if approved.

<sup>c</sup> Humalog 3 mL vials were discontinued in March 2024. Supply in channel anticipated to be depleted by end of April 2024.

**Abbreviations:** BLA = biologics license application; HCPCS = healthcare common procedure coding system; IV = intravenous; MDV = multidose vial; NA = not applicable

## References

1. Lilly to introduce lower-price insulin. Published March 4, 2019. Accessed April 11, 2024. <https://investor.lilly.com/news-releases/news-release-details/lilly-introduce-lower-priced-insulin>.
2. Insulin manufacturers authorize half-price generics. Published November 19, 2019. Accessed April 11, 2024. <https://www.uspharmacist.com/article/insulin-manufacturers-authorize-half-price-generics>.
3. Purple Book: Database of Licensed Biological Products. Updated April 9, 2024. Accessed April 11, 2024. <https://purplebooksearch.fda.gov/>.
4. Payer and Provider Insights. IPD Analytics. Accessed April 15, 2024. (subscription required). <https://clinical-pipeline.ipdanalytics.com/>.
5. Lexi-Comp Online™, Hudson, Ohio: Lexi-Comp, Inc.;2024; Accessed April 15, 2024.
6. Access Hub. IPD Analytics. Accessed April 15, 2024. (subscription required). <https://clinical-pipeline.ipdanalytics.com/>.
7. Medi-Span Price Rx. Wolters Kluwer, Waltham, MA. Accessed April 15, 2024. <https://pricerx.medispan.com>.

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Vizient, Inc.  
290 E. John Carpenter Freeway  
Irving, TX 75062-5146  
(800) 842-5146



To learn more, please contact  
Vizient Center for Pharmacy Practice Excellence,  
Evidence-Based Medicine Group at  
[pharmacyquestions@vizientinc.com](mailto:pharmacyquestions@vizientinc.com)

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