APIDRA®

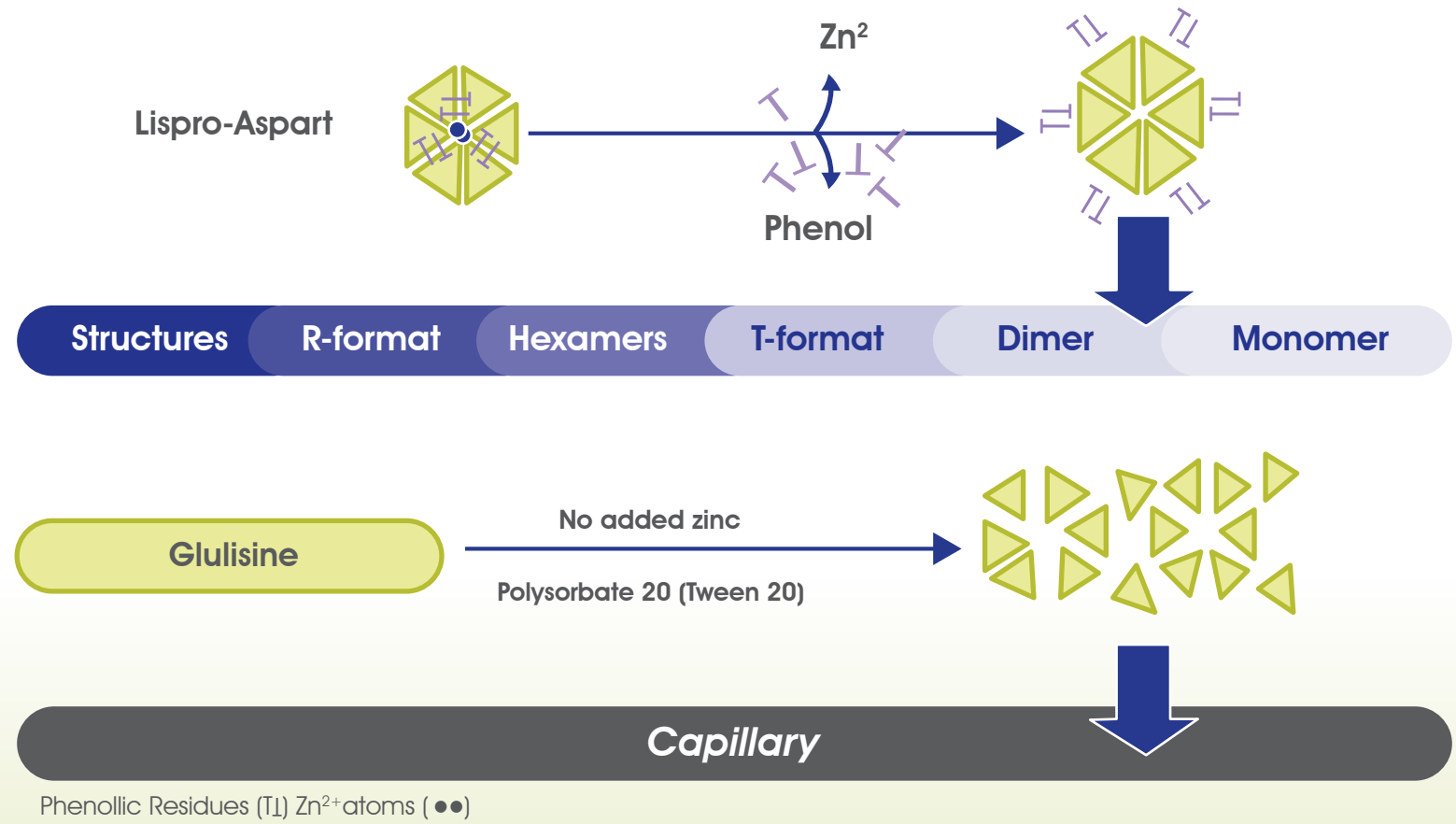
insulin glulisine

THE SPEED YOU NEED. WHEN YOU NEED IT.

sanofi

APIDRA®
insulin glulisine

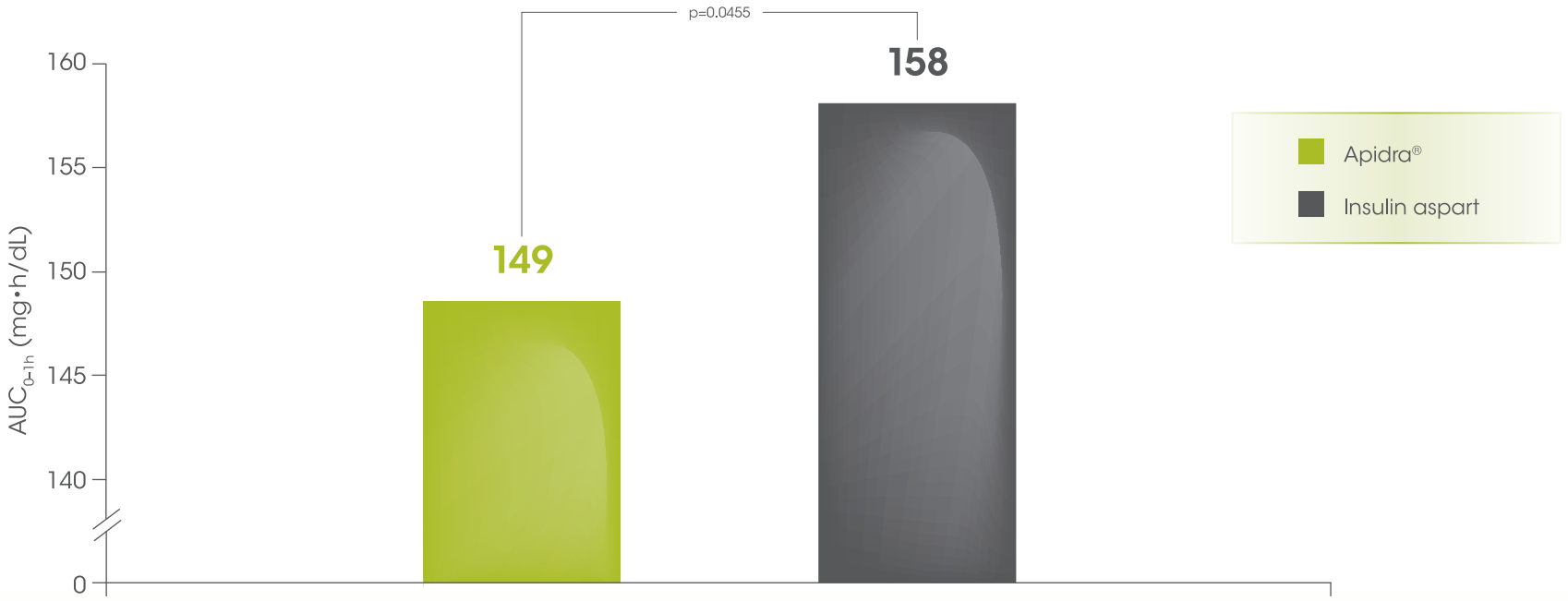
The Mechanism of Uptake from Subcutaneous Tissues[1,2]



1. Brange J, et al. Diabetes Care 1990:13;923–54.
2. Becker RH. Diabetes Technol Ther 2007;9:109–21

Apidra has an earlier effect on postprandial glucose levels than insulin aspart[1]

One hour blood glucose levels after a standard meal[1]



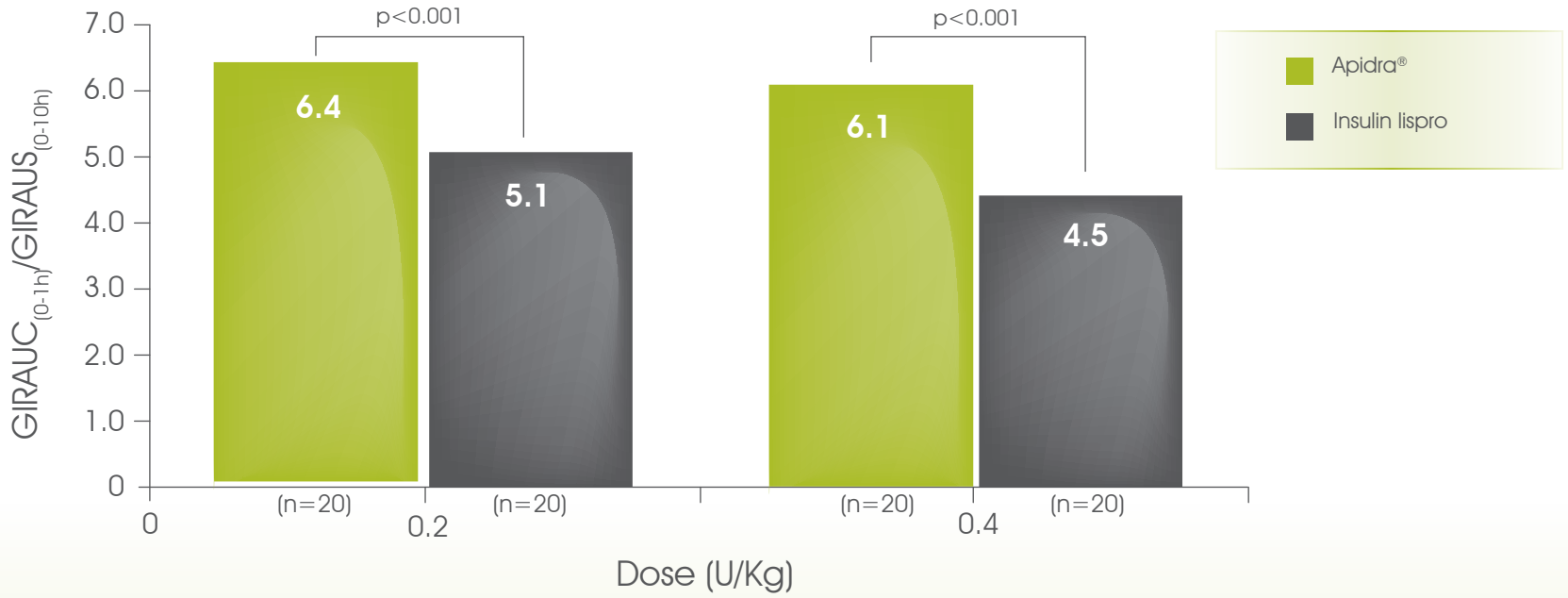
- Despite this rapid onset, only 13 (36.1%) patients receiving Apidra® experienced an episode of hypoglycemia* compared with 16 (43.2%) subjects receiving insulin aspart[1]

Apidra® reduces blood glucose levels more rapidly versus insulin aspart[1]

1. Boli GB, et al. Diabetes Obes Metab 2011; 13: 251-257.

Apidra has a faster onset of action than insulin lispro[1]

Apidra has a significantly higher proportion of total metabolic activity occurring in the first hour postdosing compared with insulin lispro[1]



Apidra has a faster onset of action, which is associated with the novel drug formulation[1]

1- Hiese T, et al. Diabetes Obes Metab. 2007;9(5): 746-53

Apidra®

Clinical Benefits

1 Effective

Improvement in glycemic control after switching to Apidra in patients with T1DM

Switching to Apidra from Aspart or Lispro:

- ✓ **Significantly decreased postprandial hyperglycemia to less than 160 mg/dL**
- ✓ **Significantly reduced HbA1c levels**

Changes in mean values of plasma glucose and glycated hemoglobin at baseline and at 6 months after using insulin Apidra in all patients:

	At baseline	After using Apidra	P-value
PG before breakfast (mg/dL)	117.7 ± 30.2	116.6 ± 26.5	0.7104
PG after breakfast (mg/dL)	183.4 ± 50.1	153.0 ± 32.2	0.0035
PG before supper (mg/dL)	126.3 ± 33.0	122.8 ± 27.1	0.4175
PG after supper (mg/dL)	203.1 ± 29.3	163.8 ± 22.9	<0.0001
HbA1c (%)	7.63 ± 0.96	7.36 ± 0.93	0.0034

n = 26. HbA1c, glycated hemoglobin; PG, plasma glucose.

Urakami T, et al. J Diabetes Investig. 2015 Jan; 6(1): 87–90.

2 Safe

Reduced frequency of hypoglycemia after switching to Apidra in patients with T1DM

Switching to Apidra from Aspart or Lispro:

✓ **Significantly decreased frequency of hypoglycemia**

Changes in frequency of hypoglycemia, mean insulin dose and percent overweight at baseline and at 6 months after using insulin Apidra in all patients:

	At baseline	After using Apidra	P-value
Frequency of hypoglycemia (time/month)	7 ± 6	4 ± 4	0.0004
Total insulin dose (unit/kg/day)	0.84 ± 0.19	0.82 ± 0.16	0.3336
Basal insulin dose (unit/kg/day)	0.36 ± 0.18	0.35 ± 0.19	0.4812
Percent overweight (%) (unit/kg/day)	6.86 ± 8.05	6.98 ± 7.61	0.7039

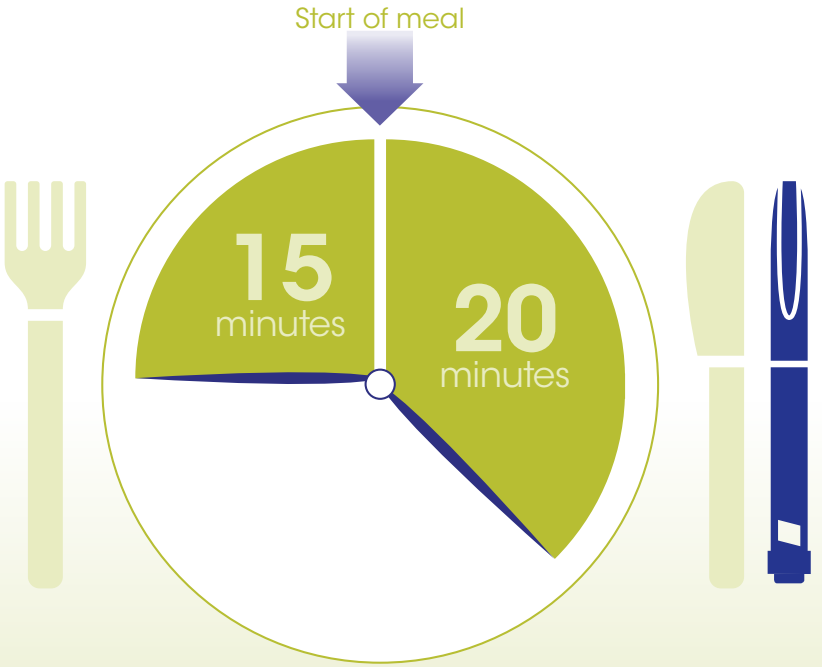
Urakami T, et al. J Diabetes Investig. 2015 Jan; 6(1): 87–90.

3 Flexible

Flexible Administration[1,2]

- ✓ Faster onset of action than insulin aspart and lispro[1,3]
- ✓ 35 minutes dosing window[4]

Administration
Before
or
After
the start of a meal[4]



1. Apidra EU Summary of Product Characteristics- September 2020.
2. Bolli GB, et al. Diabetes Obes Metab 2011; 13:251-257.
3. Hiese T, et al. Diabetes Obes Metab. 2007;9(5): 746-53 4. Apidra FDA Label

Easy Titration[1]

Start

Initial Dose: 4 IU[1]

Titrate

Adjust Dose 1-2 Units Twice Weekly Till PPBG Target is Achieved[1]

(ADA/EASD Guideline Recommendation: PPBG<180 mg/dl)[1]

1. ADA guideline 2021, Disbetes care, vol 44, supplement 1.

APIDRA® Abbreviated Prescribing Information

1. **NAME AND PRESENTATION:** Apidra 100 U/ml, solution for injection of insuline glulisine is available in a pre-filled disposable pens of 3ml for Solostar. **2.THERAPEUTIC INDICATIONS:** Treatment of adults, adolescents and children, 6 years or older with diabetes mellitus, where treatment with insulin is required. 3. **POSOLOGY AND METHOD OFADMINISTRATION:** Apidra in pre-filled pen is only suitable for subcutaneous injections. Apidra should be given by subcutaneous injection shortly (0-15 min) before or soon after meals. Apidra could be used in regimens that include an intermediate or long acting insulin or basal insulin analogue and with oral hypoglycemic agents. The dosage of Apidra should be individually adjusted. When administered as a subcutaneous injection, Apidra® must not be mixed with other medicinal products except NPH human insulin. Injection sites must be rotated within a given injection area from one injection to the next, in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. For administration details see full SmPC. Patients must be educated to use proper injection techniques and insulin. label must always be checked before each injection to avoid medication errors between Apidra and other insulins. Renal impairment & hepatic impairment: insulin requirements may be reduced. Elderly: deterioration of renal function may lead to a decrease in insulin requirements. 4. **CONTRA-INDICATIONS:** Hypersensitivity to insulin glulisine or to any of the excipients. Hypoglycemia. 5. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** Transferring a patient to a new type or brand of insulin should be done under strict medical supervision. Changes in strength, brand, type, source and/or method of manufacture may result in the need for a change in dose. In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Concomitant oral antidiabetic treatment may need to be adjusted. Adjustment of dosage may be necessary if patients undertake increased physical activity or change their usual meal plan. Conditions which may take the early warning symptoms of hypoglycemia are detailed in the full SmPC. If pioglitazone is used in combination with insulin, especially in patients with CHF risk factors, patients should be observed for signs and symptoms of heart failure, weight gain and edema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. 6. **DRUG INTERACTIONS:** Substances that may enhance or reduce the blood-glucose-lowering activity and increase susceptibility to hypoglycemia are detailed in the full SmPC. 7. **PREGNANCY AND LACTATION:** No adequate data are available. Pregnant and Breast-feeding mothers may require adjustments in insulin dose and diet. 8. **ABILITY TO DRIVE:** The patient's ability to concentrate and react may be impaired as a result of hypoglycemia or hyperglycemia or, for example, as a result of visual impairment. Patients should be advised to take precautions to avoid hypoglycemia whilst driving. 9. **UNDESIRABLE EFFECTS:** Hypoglycemia is the most frequent undesirable effect of insulin therapy. Injection site reactions and local hypersensitivity reactions. Lipodystrophy and cutaneous amyloidosis may occur at the injection site and delay local insulin absorption. Continuous rotation of the injection site within the given injection area may help to reduce or prevent these reactions For uncommon & rare adverse events, consult the full SmPC. 10. **OVERDOSAGE:** Mild hypoglycemic episodes can be treated by oral administration of glucose or sugary products. Severe hypoglycemic episodes can be treated by glucagon (0.5 to 1 mg) given intramuscularly or subcutaneously or by glucose given intravenously.11. **PHARMACODYNAMIC PROPERTIES:** ATC code: A10AB06. 12. **MARKETING AUTHORIZATION HOLDER:**Sano_-Aventis Deutschland GmbH, D-65926 Frankfurt am Main.Abbreviated Prescribing Information, Date of Revision of API: based on the EU SmPC as of Jun 2021 on last SmPC related to CCDS V12. Always refer to the full Summary of Product Characteristics (SmPC) before prescribing

1 Effective[1]

2 Safe[1]

3 Flexible[2,3,4]

References:

1.Urakami T, et al. J Diabetes Investig. 2015 Jan; 6(1): 87–90.

2.Apidra EU Summary of Product Characteristics- September 2020.

3.Bolli GB, et al. Diabetes Obes Metab 2011; 13:251-257

4.Hiese T, et al. Diabetes Obes Metab. 2007;9(5): 746-53

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