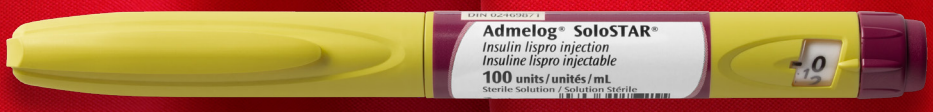
NOW AVAILABLE

Admelog®

The first and only **biosimilar** of Humalog®[1]*



Available in the **SoloSTAR® pen**, cartridges and vials[1]

ADMELOG® is indicated for the treatment of patients with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. ADMELOG® is also indicated for the initial stabilization of diabetes mellitus.

* Comparative clinical significance unknown.

Admelog®
insulin lispro
injection 100 Units/mL

SANOFI

ADMELOG® vs. Humalog®

A head-to-head study in T1DM and another in T2DM (both in adults) demonstrated:

Non-inferior HbA1c reduction at week 26 at the 0.3% non-inferiority margin[1]

	T1DM*		T2DM†	
	ADMELOG® (n=247)	Humalog® (n=249)	ADMELOG® (n=239)	Humalog® (n=246)
LS mean change from baseline	-0.42	-0.4	-0.92	-0.85
Difference (95% CI)	0.06 (-0.084 to 0.197)		-0.07 (-0.215 to 0.067)	

Safety profile[1]

- **The types, frequency and severity of adverse events were comparable between ADMELOG® and the reference biologic drug**
  - Adverse reactions observed with the reference drug included local and systemic allergic reactions, injection site reaction, lipodystrophy, pruritus, rash and hypoglycemia; insulin lispro 100 U/mL administered as a continuous subcutaneous infusion resulted in 26% of patients reporting ≥1 perceived catheter set occlusion and, in another study, 0.09 catheter occlusions/month were seen and 2.6% of patients reported infusion site reactions

T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus; LS = least square

* Open-label, 2-arm parallel, 26-week study in adult patients with T1DM who were randomized to ADMELOG® (n=253) or Humalog® (n=254), both in combination with insulin glargine, given as SC injections before or immediately after each meal in order to achieve a 2-h postprandial plasma glucose of 6.7 to 8.9 mmol/L while avoiding hypoglycemia (intention-to-treat [ITT] analysis). Mean baseline HbA1c: 8.08 for ADMELOG®, 7.99 for Humalog®.

† Open-label, 2-arm parallel, 26-week study in adult patients with T2DM who were randomized to ADMELOG® (n=253) or Humalog® (n=252), both in combination with insulin glargine, given as SC injections before or immediately after each meal in order to achieve a 2-h postprandial plasma glucose of 6.7 to 8.9 mmol/L while avoiding hypoglycemia (ITT analysis). Mean baseline HbA1c: 8.00 for ADMELOG®, 8.03 for Humalog®.

ADMELOG®

Dosing recommendations[1]*

New patients:

- Patients receiving insulin for the first time can be started on ADMELOG® **in the same manner** as they would be on animal-source or human insulin. Patients should be monitored closely during the adjustment period.

Transfer patients:

- When transferring patients to ADMELOG®, **use the same dose and dosage schedule**. Some patients switching from other insulins may require a change in dosage from that used with their previous insulins. If an adjustment is needed, it may occur with the first dose or during the first several weeks or months.
- Transferring a patient from Humalog® to ADMELOG® can be done unit-to-unit based on the previous rapid-acting insulin dose.

To achieve optimal glycemic control, changes in total daily dosage, the number of injections per day, and/or timing of injections of ADMELOG® may be necessary. Reassessment and adjustment of the basal insulin regimen, as necessary, have been shown to optimize overall glycemic control.

1:1 unit dosing

Transferring a patient from Humalog® to ADMELOG® can be done unit-to-unit based on the previous rapid-acting insulin dose.[1]

Special populations

ADMELOG® can be used in:[1]

ADULTS | **CHILDREN** | **PREGNANT PATIENTS** | **PATIENTS USING PUMPS**

Careful monitoring in pregnancy is recommended, as well as during the perinatal period in infants born to mothers with diabetes.

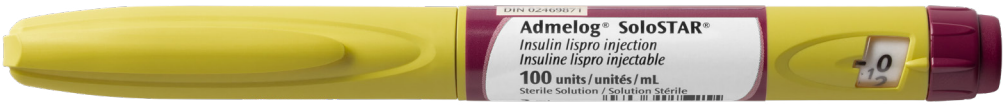
When used via a subcutaneous insulin infusion pump, should not be diluted or mixed with any other insulin.

* Please consult the Product Monograph for complete dosing and administration information.

ADMELOG®

- A Humalog® (insulin lispro) biosimilar
- **Demonstrated non-inferior to Humalog® in reducing HbA1c** at week 26 in a study in T1DM adult patients and another in T2DM adult patients[1]
- **The types, frequency and severity of adverse events were comparable** between ADMELOG® and the reference biologic drug[1]

Available in the SoloSTAR® pen[1]



- Available in cartridges for use only in Sanofi JuniorSTAR® and AllStar® PRO reusable pens
- Also available in vials

ADMELOG®:
Another option from Sanofi available to you and your patients with diabetes

Clinical use:

The indications have been granted on the basis of similarity between ADMELOG® and the reference biologic drug, Humalog®. ADMELOG® is a short-acting insulin analogue and is for use in conjunction with a longer-acting insulin, except when used in a subcutaneous insulin infusion pump.

Contraindications:

- During episodes of hypoglycemia

Most serious warnings and precautions, not discussed elsewhere in this piece:

- **Hypoglycemia** is the most common adverse effect of insulin
  - Uncorrected hypo- or hyperglycemia can cause loss of consciousness, coma or death
  - Glucose monitoring is recommended
- **Administration**
  - Give within 15 minutes before a meal; when necessary, may be given within 20 minutes after the start of a meal
  - Changes to insulin should be made cautiously, and only under medical supervision
  - Do not use if not water-clear and colourless or if a deposit of solid particles has formed on the wall of the vial or cartridge

Other relevant warnings and precautions, not discussed elsewhere in this piece:

- Hypokalemia
- Stress and concomitant illness may change insulin requirements
- Cartridges or prefilled syringes should not be used by more than one person
- Caution in patients with gastroparesis
- Do not use with thiazolidinediones (TZDs)
- Change in dose may be required when switching patients from other insulins
- Hypoglycemia
- Hyperglycemia
- Risk of local allergic reactions, injection site reactions, systemic allergic reactions and antibody formation
- Not studied in nursing mothers; nursing patients may require dose adjustments
- Renal impairment may reduce insulin requirements
- Geriatric patients
- Control of diabetes may be further complicated by diseases such as acromegaly, Cushing's syndrome, hyperthyroidism and pheochromocytoma

For more information:

Please consult the Product Monograph at **http://products.sanofi.ca/en/admelog-en.pdf** for important information relating to adverse reactions, drug interactions and dosing information, which have not been discussed in this piece. The Product Monograph is also available by calling 1-888-852-6887.

Reference: 1. ADMELOG® and ADMELOG® SoloSTAR® Product Monograph. Sanofi-aventis Canada Inc., November 22, 2019.

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INNOVATIVE MEDICINES CANADA

Admelog® insulin lispro injection 100 Units/mL

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