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ENDOCRINOLOGY & DIABETES



# Making Sense of Biosimilar Insulins: What You Need to Know

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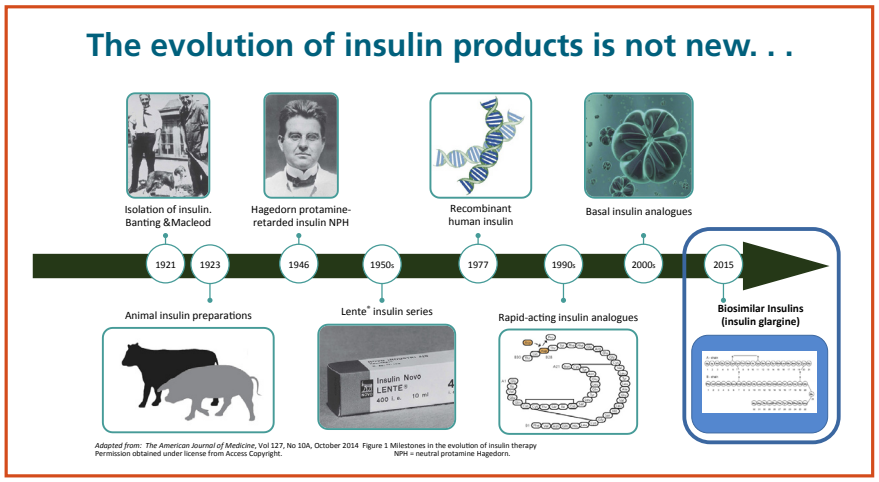
The landscape of insulins used for type 1 and type 2 diabetes has never been as complicated as it is today. Patients are expected to keep track of both oral and injectable medications, often also needing to distinguish between brand names and generic names. Complicating matters further, biosimilar insulins are also currently authorized and available in Canada. This is important for both patients and prescribers, especially patients that rely on public payers for medication coverage (or private payers who mimic public formularies). Their introduction is to help reduce the cost of insulin in Canada and around the world, making insulin more affordable for patients and payers.




There are 3 biosimilar insulins available in Canada: The basal insulin glargine (U-100) is available as the reference insulin, Lantus®, and as the biosimilar insulin, Basaglar®. Prandial insulins lispro (U-100) is available as the reference insulin, Humalog®, and as the biosimilar insulin, Admelog®, and aspart is available as the reference, Novorapid®, and as the biosimilar, Trurapi® .

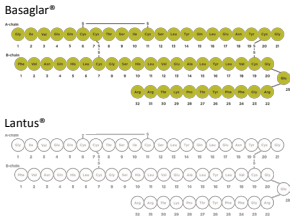
## What is a Biosimilar Insulin?

Health Canada refers to biosimilars as biosimilar biologic drugs (previously known as subsequent entry biologics). Biosimilars are not

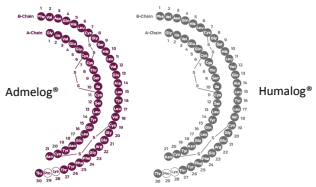
"Biosimilars are not the same as generic medications"

## Biosimilar Insulins in Canada

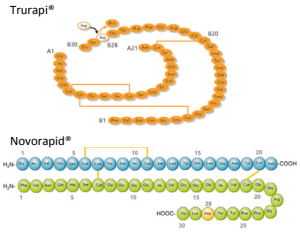
**Glargine (U-100)**




**Lispro (U-100)**




**Aspart (U-100)**




the same as generic medications. Generic medication contains identical ingredients to the reference (brand name medication). Often if a medication is sold under only a generic name, its patent has expired. Biosimilar medication is highly comparable but not necessarily identical to the reference. Biosimilar biologics often have large and complex structures; made from living cells in a complicated manufacturing process.

Health Canada has a designated an approval process for biosimilar biologic drugs since 2010. Biosimilars must submit data to demonstrate similarity to the reference biologic under the following categories: structure & function, human clinical trials, comparative studies evaluating efficacy and safety, and manufacturing quality control. Overall, this approval process is more stringent than the process required for generics, but less stringent than the process required for new drugs. Similar amounts of analytical and pharmacokinetic testing are required, but clinical trial data requirements are relatively less.

In randomized clinical trials, Basaglar® demonstrated similar efficacy and safety to the reference insulin, Lantus® in patients with both type 1 and type 2 diabetes. Similarly, Admelog® and Trurapi® demonstrated the same compared to the reference insulins, Humalog® and Novorapid®, respectively. Risks of hypoglycemia and other treatment emergent adverse effects were also comparable between the biosimilar and reference insulins. There is theoretical potential for an immune system response when exposed to a biologic agent. In a systematic review, biosimilar insulins demonstrated similar proportion of patients developing antibodies compared to reference groups. all demonstrated similar proportion of patients developing antibodies between the biosimilar and reference groups[1]

> "Dosing of biosimilar insulins is also the same as the reference for initiating, switching, and titrating."

## Insulin Prescription

Choose insulin(s) from one of the columns and then complete the dosing and titration column.

Prescriber's Name: | Patient's Name:
Address: | Address:
Tel: Fax: | Tel:

| STEP 1: Choose Insulin Type | | | | STEP 2: Dosing and Titration |
|---|---|---|---|---|
| **BASAL**<br>**Long-acting analogues** (Clear) | ☐ **Basaglar**™<br>☐ Cartridge<br>☐ Kwikpen® (prefilled) | ☐ **Levemir®**<br>☐ Cartridge<br>☐ FlexTouch® (prefilled)<br>☐ **Tresiba®**<br>☐ FlexTouch® 100 U/mL (prefilled)<br>☐ FlexTouch® 200 U/mL (prefilled) | ☐ **Lantus®**<br>☐ Cartridge ☐ Vial<br>☐ SoloSTAR® (prefilled)<br>☐ **Toujeo®**<br>☐ SoloSTAR® (prefilled)<br>☐ DoubleSTAR® (prefilled) | **Starting dose:**<br>_____ units at _____<br>Increase dose by _____ units every _____ until fasting blood glucose has reached the patient's individual target of _____ mmol/L. |
| **Intermediate-acting** (Cloudy) | ☐ **Humulin® N**<br>☐ Cartridge ☐ Vial<br>☐ Kwikpen® (prefilled) | ☐ **Novolin® ge NPH**<br>☐ Cartridge<br>☐ Vial | | |
| **PRANDIAL (BOLUS)**<br>**Rapid-acting analogues** (Clear) | ☐ **Humalog®**<br>☐ Cartridge ☐ Vial<br>☐ Kwikpen® (prefilled)<br>☐ **Humalog® 200 units/mL**<br>☐ Kwikpen® (prefilled) | ☐ **Fiasp®**<br>☐ Cartridge ☐ Vial<br>☐ FlexTouch® (prefilled)<br>☐ **NovoRapid®**<br>☐ Cartridge ☐ Vial<br>☐ FlexTouch® (prefilled) | ☐ **Apidra®**<br>☐ Cartridge ☐ Vial<br>☐ SoloSTAR® (prefilled)<br>☐ **Admelog™**<br>☐ Cartridge ☐ Vial<br>☐ SoloSTAR® (prefilled) | **Starting dose:**<br>_____ units ac breakfast<br>_____ units ac lunch<br>_____ units ac supper |
| **Short-acting** (Clear)<br>Give 30 minutes before meal. | ☐ **Humulin® R**<br>☐ Cartridge<br>☐ Vial | ☐ **Novolin® ge Toronto**<br>☐ Cartridge<br>☐ Vial | | |
| **PREMIXED**<br>**Premixed analogues** (Cloudy) | ☐ **Humalog® Mix25**™<br>☐ Cartridge<br>☐ Kwikpen® (prefilled)<br>☐ **Humalog® Mix50**™<br>☐ Cartridge<br>☐ Kwikpen® (prefilled) | ☐ **NovoMix® 30**<br>☐ Cartridge | | **Starting doses:**<br>_____ units ac breakfast<br>_____ units ac supper<br>Increase breakfast dose by _____ units every day until pre-supper blood glucose has reached the target of _____ mmol/L.<br>Increase pre-supper dose by _____ units every day until fasting blood glucose has reached the target of _____ mmol/L.<br>Beware of hypoglycemia post-breakfast or post-supper. Stop increasing dose if hypoglycemia occurs. |
| **Premixed regular** (Cloudy)<br>Give 30 minutes before meal. | ☐ **Humulin® 30/70**<br>☐ Cartridge<br>☐ Vial | ☐ **Novolin® ge 30/70**<br>☐ Cartridge ☐ Vial<br>☐ **Novolin® ge 40/60**<br>☐ Cartridge<br>☐ **Novolin®ge 50/50**<br>☐ Cartridge | | |
| **PEN DEVICE**<br>Required if insulin cartridges selected. Insulin pen should match the insulin brand. | ☐ **HumaPen® Savvio**™<br>☐ **HumaPen LUXURA® HD** | ☐ **NovoPen® 4**<br>☐ **NovoPen Echo®**<br>☐ **NovoPen® 5** | ☐ **ClikSTAR**™ | |
| **OTHER SUPPLIES** | ☐ **Pen needles (if using a pen):** Check needle size (refer to back for information): ☐ 4mm ☐ 5mm ☐ 6mm ☐ 8mm **OR**<br>☐ At discretion of pharmacist<br>☐ Glucose test strips ☐ Lancets ☐ Insulin Syringe (if using vials) ☐ Ketone Strips (if applicable)<br>☐ Glucagon ☐ Nasal Glucagon | | | |
| **QUANTITY and REPEATS** | **Insulin** Mitte: _____ boxes Repeats x _____ | | **Supplies** Mitte: _____ boxes Repeats x _____ | |

Signature: Print Name: Date: License #:



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## What do I Need to Know about Biosimilar Insulins?

Biosimilar insulins, Basaglar®, Admelog® and Trurapi®, have the same indications as the reference insulins, Lantus®, Humalog® and Novorapid®, respectively. Dosing of biosimilar insulins is also the same as the reference for initiating, switching, and titrating. Diabetes Canada has recently launched an insulin initiation tool to facilitate selecting the type of insulin and device, dosing, and titration.

Health Canada's approval of a biosimilar does not mean the biosimilar is interchangeable. This is determined by each province. In Ontario, biosimilar insulins are not interchangeable. Some provincial formularies (Quebec, Alberta & British Colombia) have instituted biosimilars policies requiring the use of a biosimilars for new or existing patients to receive or maintain provincial formulary coverage. For cash paying patients, biosimilar insulins are generally less expensive than the reference insulin. Diabetes Canada recommends health care providers to consider biosimilar insulins as the first treatment option for insulin-naive patients where these represent a cost-effective advantage, and to discuss and agree jointly with the person living with diabetes on the appropriate use of biosimilar insulin, providing clear and sufficient information.

> "Diabetes Canada recommends health care providers to consider biosimilar insulins as the first treatment option for insulin-naive patients where these represent a cost-effective advantage. . ."

> "Biosimilar insulins are similar but not identical to the reference insulin, and offer equivalent efficacy, safety, and dosing at a reduced cost."

## How do I Set Up my Patient for Success?

My experience with biosimilar insulins has generally been positive. In my practice, biosimilar insulins are utilized exactly like the reference insulin. Since patients often attribute worsening glycemic control to changes in medications, it is particularly important to provide counselling that another similar insulin exists (and may even be interchangeable depending on the province you live in). Further, when patients using insulin are "forced" to switch from their existing insulin to a biosimilar due to changes in availability, cost, or coverage, then their views are often tainted to any potential benefit. Diabetes Canada recommends that governments and private insurers do not implement forced non-medical switching policies that require patients established on treatment to switch from a reference biologic drug to a biosimilar insulin.

The global burden of diabetes and rising cost of insulins are significantly impacting health care expenditure thereby limiting access to treatment for more of our patients. Individualizing antihyperglycemic treatment already involves the consideration of cost and coverage. Biosimilar insulins are similar but not identical to the reference insulin, and offer equivalent efficacy, safety, and dosing at a reduced cost. As with any diabetes treatment, careful consideration, effective conversation, and tailoring of treatment to patient needs will result in the best outcome for patients.

LMC Healthcare

# Diabetes Awareness Month

Please share this invitation with your patients for the LMC Diabetes Awareness Month free webinar series!

## Ask a Pharmacist

- **November 10 at 7:30 PM EST**
- Ask your medication questions, side effects concerns, injection issues, insurance and drug coverage, immunizations, smoking cessation, glucometers, Libre or Dexcom troubleshooting, etc.
- Hosted by Certified Diabetes Educator Pharmacists Meena & Elena

## Ask Your Diabetes Team!

- **November 24 at 7:30 PM EST**
- Ask about diet, exercise, foot issues, eye concerns, medications, device troubleshooting, coverage programs, - or anything else diabetes-related that you may be wondering about!
- Panelists include a CDE Dietitian, CDE Pharmacist, Chiropodist and Optician

## Multilingual & Specialty Workshops

- **Throughout November** - day and evening options available
- Cantonese, English, French, Hindi, Punjabi
- Variety of topics including Living with Diabetes, Weight Management, Meal Planning and more!
- Hosted by Certified Diabetes Educator Dietitians and Nurses

## Scan Me!

**Sign up here: http://bit.ly/lmcworkshops**

**Thank you for sharing these resources with your patients!**

LMC Diabetes & Endocrinology | LMC Pharmacy | LMC Chiropody & Foot Care | LMC Optometry & Eye Care

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