IN A SEVERE HYPOGLYCEMIA EMERGENCY

READY FOR RESCUE

Baqsimi™
glucagon nasal powder 3 mg

THE FIRST AND ONLY GLUCAGON WITH NASAL ADMINISTRATION[1]

BAQSIMI™ is indicated for the treatment of severe hypoglycemic reactions which may occur in the management of insulin treated patients with diabetes mellitus, when impaired consciousness precludes oral carbohydrates.[2]

DIABETES CANADA GUIDELINES FOR HYPOGLYCEMIA

Hypoglycemia severity[3]

Mild	Moderate	Severe
Autonomic symptoms are present. The individual is able to self-treat.	Autonomic and neuroglycopenic symptoms are present. The individual is able to self-treat.	Typically <2.8 mmol/L Individual requires assistance of another person. Unconsciousness may occur.

MAJOR RISK FACTORS FOR SEVERE HYPOGLYCEMIA

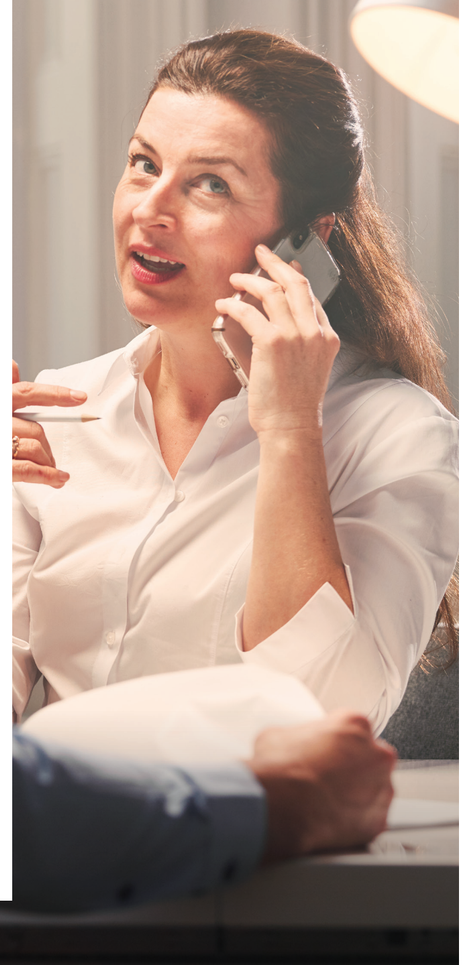
For patients with **Type 1 diabetes**:[3]

- Prior episode of severe hypoglycemia
- Current low A1C (<6.0%)
- Hypoglycemia unawareness
- Long duration of insulin therapy
- Autonomic neuropathy
- Children unable to detect and/or treat mild hypoglycemia on their own
- Adolescence

For patients with **Type 2 diabetes**:[3]

- Advancing age
- Severe cognitive impairment
- Poor health literacy
- Food insecurity
- Increased A1C
- Hypoglycemia unawareness
- Duration of insulin therapy
- Renal impairment
- Neuropathy

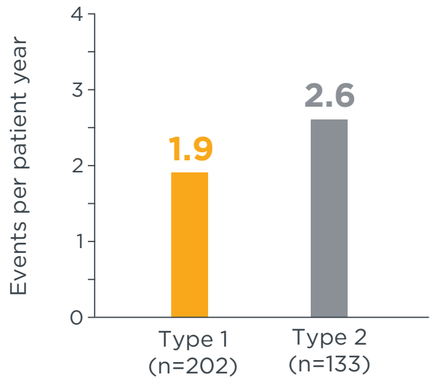
Events are more common in those with a history of hypoglycemia and those with longer duration of insulin treatment.[3]



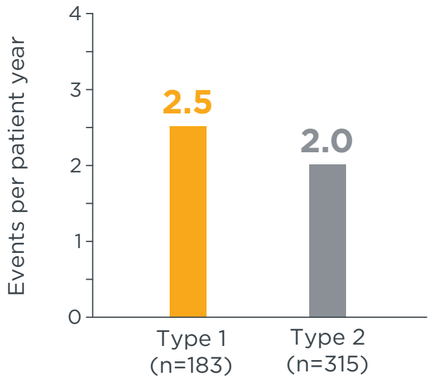
PATIENTS WITH TYPE 1 or TYPE 2 DIABETES COULD BE AT RISK

Hypoglycemia is most frequent in people with Type 1 diabetes, and people with Type 2 diabetes managed with insulin[3]

Average number of severe hypoglycemia events per patient year in Canadian patients on insulin



Adapted from Leiter, *et al.*[4*]



Adapted from Aronson, *et al.*[5†]
Based on retrospective data. The same study also used prospective data in a separate analysis.

* A 2005 survey-based retrospective observational study designed to quantify the number of hypoglycemic episodes experienced and to assess the effects that hypoglycemia and fear of hypoglycemia have on daily activities, glycemic management and post-episode lifestyle infringements. The study was conducted at 4 Canadian centres with adult patients diagnosed with either Type 1 or Type 2 diabetes, treated with insulin alone or in combination with oral agents for ≥1 year.[4]

† A 2018 non-interventional, 6-month retrospective, 4-week prospective study of Canadian adult patients with Type 1 and Type 2 diabetes treated with insulin >12 months. Data were collected using self-assessment questionnaires and patient diaries. The primary endpoint was the proportion of patients experiencing ≥1 hypoglycemic event during the 4-week prospective observational period.[5]

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BAQSIMI: DESIGNED WITH SEVERE HYPOGLYCEMIA TREATMENT IN MIND

- **Dry powder** form of glucagon[2]
- Single use, **pre-filled nasal** device with 3 mg dose[2]
- **Ready to use** with no reconstitution or priming required[2]
- Does **not need to be refrigerated**
  - Can be stored up to 30°C (86°F) in the shrink-wrapped tube provided[2]
- Absorbed passively via the intranasal route — **no inhalation required**[2]
- BAQSIMI has a shelf life of 2 years from the date of manufacture[4]
- Each BAQSIMI device contains a single dose and is available as a 1-pack[2]

Do not remove shrink wrap or open the tube until ready to use.[2]

Formulation invented in Canada

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BAQSIMI: SIMPLE TO ADMINISTER IN A CASE OF SEVERE HYPOGLYCEMIA

HOLD

Hold the device between fingers and thumb. **Do not press plunger before insertion into the nose. Otherwise, the single dose in the device will be lost.**[2]

INSERT

Insert the tip gently in a nostril until the fingers touch the outside of the nose.[2]

PUSH

Push the plunger all the way in. **The dose is complete when the green line is no longer showing.**[2]

Caregivers should read the Patient Medication Information carefully before using BAQSIMI. **Do not test the device before use**, as it contains only one dose of glucagon and cannot be reused.[2]

AFTER GIVING THE DOSE:[2,3]

1. Remove the tip from nose and **throw away the used device and tube**.

2. **Call for medical help right away.**

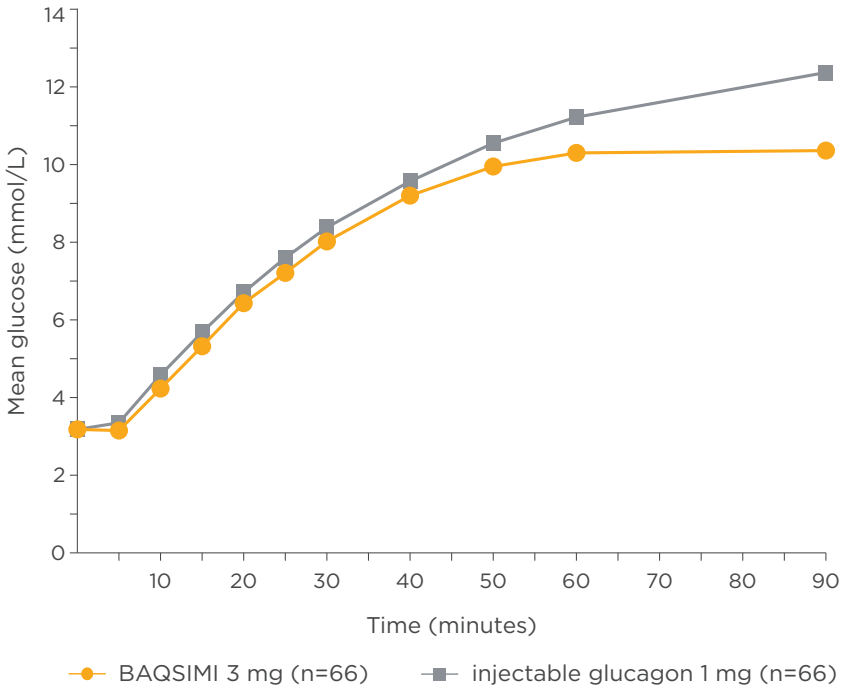
3. If the person with low blood sugar is unconscious, turn the person on their side.

4. Patients usually respond within 15 minutes.

5. **Encourage the person to eat as soon as they can safely swallow.** Give them a fast-acting source of sugar, like juice or regular soda. Then give them a long-acting source of sugar, like cheese and crackers, peanut butter, or a sandwich with meat.

BAQSIMI BEGAN RAISING MEAN PLASMA GLUCOSE AS EARLY AS 5 MINUTES[2,5]*

Mean plasma glucose concentrations over time with BAQSIMI[2,5]

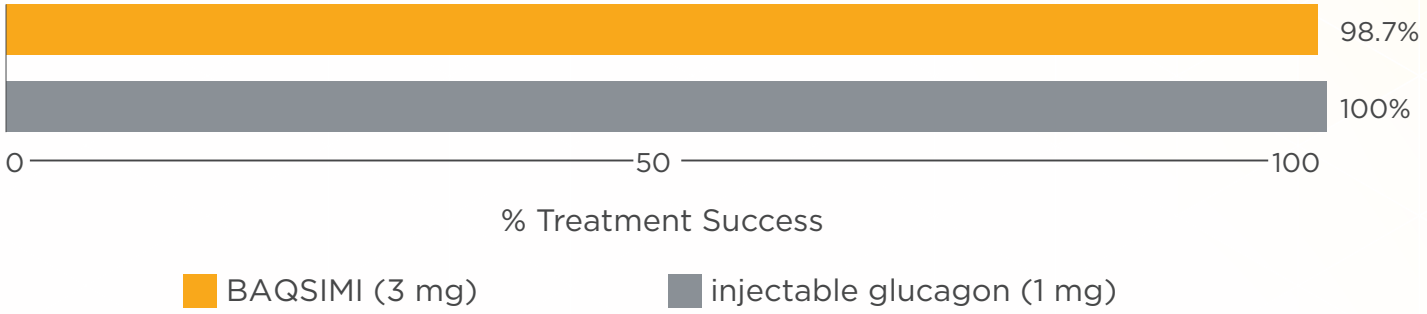


Nasal congestion does not impact the absorption of BAQSIMI[2]

* A randomized, multicenter, crossover noninferiority trial was conducted in adult patients with Type 1 diabetes. Hypoglycemia was induced with intravenous insulin and treated by 3 mg intranasal glucagon or 1 mg intra-muscular glucagon. Plasma glucose was measured after each treatment was given.[5]

BAQSIMI DEMONSTRATED COMPARABLE EFFICACY TO INJECTABLE GLUCAGON IN ADULT PATIENTS WITH TYPE 1 DIABETES[2]

Treatment success for BAQSIMI and injectable glucagon[2]*



Treatment success was defined as the percentage of patients with either an increase in blood glucose to ≥3.9 mmol/L or an increase of ≥1.1 mmol/L from blood glucose nadir within 30 minutes.[2]

Nadir is defined as minimum glucose measurement at the time of or within 10 minutes after glucagon administration. The mean nadir blood glucose was 2.5 mmol/L for BAQSIMI and 2.7 mmol/L for injectable glucagon.[2]

* Study IGBC was a randomized, multicenter, open-label, 2-period, crossover study in adult patients with Type 1 diabetes (n=77) that compared the efficacy of a single 3 mg dose of BAQSIMI versus 1 mg injectable glucagon for treatment of hypoglycemia induced by intravenous insulin with a target blood glucose of <2.8 mmol/L. The primary efficacy measure was the proportion of patients achieving treatment success.[2]

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SIMULATED SEVERE HYPOGLYCEMIA RESCUE STUDY*

Successful administration (% of participants who were able to deliver a full dose)[6]

	BAQSIMI	INJECTABLE GLUCAGON
		
Trained caregivers (n=16)	94%	13%
Untrained individuals (n=15)	93%	0%
Mean time to administration by caregivers (minutes)	0.27	1.89

* A study of administration rates, time to administration, and experience of administering BAQSIMI vs. injectable glucagon to a mannequin, by trained and untrained users, during a simulated severe hypoglycemia event. Trained caregivers received BAQSIMI and injectable glucagon administration instructions from the person with diabetes for whom they were caregivers. Untrained users were not associated with a person with diabetes, had no prior experience with glucagon, and were shown what each glucagon treatment looked like immediately before simulation.[6]

BAQSIMI ADVERSE REACTIONS IN ADULT PATIENTS

Adverse reactions (%) in adult Type 1 and Type 2 diabetes patients with an incidence ≥5%[2]

	IGBC: Type 1 and Type 2 diabetes	
Adverse Reactions	**BAQSIMI 3 mg (n=83) %**	**Injectable glucagon 1 mg (n=82) %**
Eye disorders		
Lacrimation increased	8.4	1.2
Gastrointestinal disorders		
Nausea	21.7	26.8
Vomiting	15.7	11.0
General disorders and administration side conditions		
Fatigue	8.4	8.5
Nervous system disorders		
Headache	20.5	8.5
Respiratory, thoracic and mediastinal disorders		
Nasal discomfort	9.6	0
Nasal congestion	8.4	1.2

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Are your patients with diabetes prepared for a severe hypoglycemia emergency?

We got their BAQ!

BAQSIMI resources

The people around the person with diabetes, including friends, family, and colleagues, should **know where BAQSIMI is located and when and how to use it**.[2]

With the Got Your BAQ resources, we're all about helping your patients feel more prepared in managing severe hypoglycemia. We're here to give helpful educational information and tools for BAQSIMI.

When your patients get BAQSIMI, we've got their BAQ.

Visit BAQSIMI.ca for more tools and resources

Scan the QR code above to access BAQSIMI.ca

Clinical use:[2]

BAQSIMI has not been studied in pediatric patients less than 4 years old.

Limited clinical trial experience has not identified difference in responses between elderly (≥65 years of age) and younger patients.

Contraindications:[2]

- Hypersensitivity to glucagon or to any ingredient in the formulation or container
- Pheochromocytoma
- Insulinoma

Most serious warnings and precautions:[2]

Lack of response: BAQSIMI should be given only in patients where impaired consciousness precludes oral carbohydrates. After intranasal administration of BAQSIMI, the patient will normally respond within 15 minutes. If the patient does not respond within 15 minutes, intravenous glucose must be administered as soon as possible.

States of starvation, adrenal insufficiency or chronic hypoglycemia: Because glucagon is of little or no help in these cases, intravenous glucose should be used for the treatment of hypoglycemia in these conditions.

Other relevant warnings and precautions:[2]

- Cardiovascular effects
- Driving and operating machinery
- Pheochromocytoma
- Insulinoma
- Sensitivity and resistance to glucagon
- Pregnant women
- Breast-feeding
- Pediatrics (<4 years of age)
- Geriatrics (>65 years of age)
- Use in patients with Type 2 diabetes taking sulfonylureas
- Use with alcohol
- Monitoring and laboratory tests

For more information:

Consult the product monograph at http://pi.lilly.com/ca/baqsimi-ca-pm.pdf for additional important information relating to warnings and precautions, adverse reactions, drug interactions and dosing information which have not been discussed in this piece. The product monograph is also available by calling 1-888-545-5972.

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IN A SEVERE HYPOGLYCEMIA EMERGENCY, BAQSIMI IS:

Portable dry nasal powder glucagon[2]

Comparable in efficacy to injectable glucagon[2]

Successfully administered by trained and untrained persons[6]

Help prepare your patients with diabetes and those around them by prescribing BAQSIMI

Formulation invented in Canada

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Prescription not required. However, may assist in obtaining insurance coverage.

References: 1. Eli Lilly Canada Inc. Data on file. **2.** BAQSIMI Product Monograph. Eli Lilly Canada Inc. September 25, 2019. **3.** Diabetes Canada Clinical Practice Guidelines Expert Committee. Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. *Can J Diabetes* 2018;42 (Suppl 1):S1-S325. **4.** Eli Lilly Canada Inc. Data on file. **5.** Rickels MR, Ruedy KJ, Foster NC, *et al.* Nasal glucagon for the treatment of insulin-induced hypoglycemia in adults with type 1 diabetes: a randomized crossover non-inferiority study. *Diabetes Care* 2016;39:264-270. **6.** Yale J-F, Dulude H, Egeth M, *et al.* Faster use and fewer failures with needle-free nasal glucagon versus injectable glucagon in severe hypoglycemia rescue: a simulation study. *Diabetes Technology & Therapeutics* 2017;19(7):1-10.

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