ZEGALOGUE® is indicated for the treatment of severe hypoglycemia in adults and children with diabetes aged 6 years and older.[1]

Indication and Usage

ZEGALOGUE® (dasiglucagon) injection is indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above.

Important Safety Information

Contraindications

ZEGALOGUE® is contraindicated in patients with pheochromocytoma because of the risk of substantial increase in blood pressure and in patients with insulinoma because of the risk of hypoglycemia.

Please see additional Important Safety Information throughout and Full Prescribing Information.

ZEGALOGUE®
(dasiglucagon) injection
0.6 mg / 0.6 mL

A RAPID-ACTING RESCUE TREATMENT

Primary Efficacy End Point: MEDIAN TIME TO PLASMA GLUCOSE RECOVERY[1]

ACROSS 3 CLINICAL TRIALS* (*p*<0.001 VS PLACEBO)

ZEGALOGUE®
(dasiglucagon)

10-MINUTE
PLASMA GLUCOSE
RECOVERY

VS

PLACEBO

40-MINUTE RECOVERY
TRIAL A IN ADULTS*

35-MINUTE RECOVERY
TRIAL B IN ADULTS*

30-MINUTE RECOVERY
TRIAL C IN ADOLESCENTS
AND CHILDREN (AGED 6-17 YEARS)*

***Trial A: ZEGALOGUE® n=82, placebo n=43; Trial B: ZEGALOGUE® n=34, placebo n=10; Trial C: ZEGALOGUE® n=20, placebo n=11.[1]**

Study Design

The efficacy of ZEGALOGUE® was demonstrated in 3 randomized, double-blind, placebo-controlled, multicenter clinical trials (Trials A, B, and C) in patients with type 1 diabetes. Trial A (N=170) and Trial B (N=45) were conducted in adult patients. Trial C (N=42) was conducted in pediatric patients aged 6-17 years. In all 3 trials, patients were randomized to receive subcutaneous doses of ZEGALOGUE® 0.6 mg, placebo, or (in Trials A and C) glucagon for injection 1.0 mg, following controlled insulin-induced hypoglycemia. During this procedure, a plasma glucose concentration of <60 mg/dL was targeted in Trials A and B, whereas the target was <80 mg/dL in Trial C. The primary efficacy end point for all 3 trials was time to plasma glucose recovery (treatment success), defined as an increase in blood glucose of ≥20 mg/dL from time of administration of study drug, without additional intervention within 45 minutes. In Trials A and B, plasma glucose values were collected and assessed at pre-dose, and at 4, 6, 8, 10, 12, 15, 17, 20, 25, 30, 40, 45, 50, 60, 75, 90 minutes after treatment. Trial C assessed plasma glucose at the same time points as did Trials A and B, with the exception of the 25-, 40-, 50-, 75- and 90-minute post-treatment time points. The primary hypothesis test was superiority of ZEGALOGUE® versus placebo. There was no formal hypothesis test of ZEGALOGUE® versus glucagon for injection.[1]

MOST COMMON ADVERSE REACTIONS

across adult and pediatric trials

Adult Trials[1]

Adverse reactions occurring in ≥2% and more frequently than with placebo in ZEGALOGUE®-treated adult patients within 12 hours of treatment in 2 placebo-controlled trials.

Adverse Reaction Type	ZEGALOGUE® (n=116) % of adult patients	Placebo (n=53) % of adult patients
Nausea	57	4
Vomiting	25	2
Headache	11	4
Diarrhea	5	0
Injection site pain	2	0

Pediatric Trial (aged 6-17 years)[1]

Adverse reactions occurring in ≥2% and more frequently than with placebo in ZEGALOGUE®-treated pediatric patients within 12 hours of treatment in 1 placebo-controlled trial.

Adverse Reaction Type	ZEGALOGUE® (n=20) % of pediatric patients	Placebo (n=11) % of pediatric patients
Nausea	65	0
Vomiting	50	0
Headache	10	0
Injection site pain	5	0

Important Safety Information (cont'd)

Warnings and Precautions

- ZEGALOGUE® is contraindicated in patients with pheochromocytoma because glucagon products may stimulate the release of catecholamines from the tumor. If the patient develops a substantial increase in blood pressure and a previously undiagnosed pheochromocytoma is suspected, 5 to 10 mg of phentolamine mesylate, administered intravenously, has been shown to be effective in lowering blood pressure.

Please see additional Important Safety Information throughout and Full Prescribing Information.

ZEGALOGUE®
(dasiglucagon) injection
0.6 mg / 0.6 mL

BE ZEGALOGUE® (DASIGLUCAGON) READY

Available in a single-dose prefilled syringe and compact autoinjector.

Single-dose prefilled syringe

Compact autoinjector

Medicine window turns red to indicate a full dose was given

Hard protective case

No reconstitution needed for at-home or on-the-go administration.[1]

Images are not actual size. For illustrative purposes only.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- In patients with insulinoma, administration of glucagon products may produce an initial increase in blood glucose; however, ZEGALOGUE® administration may directly or indirectly (through an initial rise in blood glucose) stimulate exaggerated insulin release from an insulinoma and cause hypoglycemia. ZEGALOGUE® is contraindicated in patients with insulinoma. If a patient develops symptoms of hypoglycemia after a dose of ZEGALOGUE®, give glucose orally or intravenously.

Please see additional Important Safety Information throughout and Full Prescribing Information.

AVAILABLE IN A 2-PACK*

Portable to fit your patient's lifestyle, at home or on the go

Detailed Storage Instructions:

In the refrigerator

ZEGALOGUE® (dasiglucagon) injection can be stored in a refrigerator (36 °F to 46 °F) until the printed expiration date on the product.[1]

- Must be kept away from the cooling element[1]
- Must not be frozen[1]

Must not be returned to the refrigerator once removed and stored at room temperature.[1]

At room temperature

ZEGALOGUE® can be stored at room temperature (68 °F to 77 °F) for up to 12 months once removed from refrigeration or until printed expiration date on the product (whichever comes first).[1]

Must not be returned to the refrigerator once removed and stored at room temperature.[1]

Instruct your patients and their caregivers to:

- Record the date when ZEGALOGUE® was removed from the refrigerator in the space provided on the protective case[1]
- Store in the provided protective case and protect from light[1]
- **Discard ZEGALOGUE® after the end of the 12-month period at room temperature storage, or after the expiration date stated on the product, whichever comes first[1]**

***Also available in a 1-pack.**

To ensure that ZEGALOGUE® is always available, after using ZEGALOGUE®, remember to always replace it with a new ZEGALOGUE® injection.

ZEGALOGUE®
(dasiglucagon) injection
0.6 mg / 0.6 mL

PRESCRIBING IN AN EMR

a 1-pack or 2-pack single dose of ZEGALOGUE® (dasiglucagon) injection

USE THE INFORMATION BELOW WHEN WRITING A PRESCRIPTION FOR ZEGALOGUE®

Rx

Drug Name: ZEGALOGUE® (dasiglucagon) injection
Strength: 0.6 mg/0.6 mL
Dosage Form: Autoinjector or prefilled syringe

Quantity: 0.6 mL (1-pack) or 1.2 mL (2-pack) **(see below)**
Refills: [Number of refills]
For 2-pack: Dispense as a 2-pack

PRESCRIPTION/PACKAGE SIZE	QUANTITY (mL)
Autoinjector 1-pack	0.6
Autoinjector 2-pack	1.2
Prefilled syringe 1-pack	0.6
Prefilled syringe 2-pack	1.2

Most EMR pick lists will feature 1 occurrence for each presentation of ZEGALOGUE®. EMR systems vary. This information is intended to provide suggestions when prescribing ZEGALOGUE® via an EMR and may not be applicable to all EMR systems.

EMR, electronic medical record.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- Allergic reactions have been reported with glucagon products; these include generalized rash, and in some cases anaphylactic shock with breathing difficulties and hypotension. Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions.
- ZEGALOGUE® is effective in treating hypoglycemia only if sufficient hepatic glycogen is present. Patients in states of starvation, with adrenal insufficiency or chronic hypoglycemia may not have adequate levels of hepatic glycogen for ZEGALOGUE® administration to be effective. Patients with these conditions should be treated with glucose.

Please see additional Important Safety Information throughout and Full Prescribing Information.

ARE YOUR PATIENTS PREPARED FOR THE MOMENTS THAT MATTER?

- Have you checked with your patients to make sure that their **glucagon rescue treatment** hasn't expired?
- Which of your patients could benefit from a **rapid-acting rescue** treatment for **severe hypoglycemia**?
- Would any of your patients benefit from a portable prefilled device designed for **at home** or **on the go**?
- Do your patients know the **signs** and **symptoms** of **severe hypoglycemia**?

Visit novomedlink.com/diabetes to learn more

Actor portrayals.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Adverse Reactions

- The most common adverse reactions (≥2%) associated with ZEGALOGUE® in adults were nausea, vomiting, headache, diarrhea and injection site pain; in pediatrics: nausea, vomiting, headache and injection site pain.

Drug Interactions

- Patients taking beta-blockers may have a transient increase in pulse and blood pressure when given ZEGALOGUE®. In patients taking indomethacin, ZEGALOGUE® may lose its ability to raise blood glucose or may produce hypoglycemia. ZEGALOGUE® may increase the anticoagulant effect of warfarin.

Please see additional Important Safety Information throughout and Full Prescribing Information.

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Please see additional safety information in the Full Prescribing Information.

Reference: 1. ZEGALOGUE® [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc.; 2023.

ZEGALOGUE®
(dasiglucagon) injection
0.6 mg / 0.6 mL

novo nordisk®