

# ZEGALOGUE- dasiglucagon injection, solution

## Zealand Pharma US, Inc

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### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ZEGALOGUE<sup>®</sup> safely and effectively. See full prescribing information for ZEGALOGUE.

## ZEGALOGUE (dasiglucagon) injection, for subcutaneous use

### Initial U.S. Approval: 2021

#### INDICATIONS AND USAGE

ZEGALOGUE is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above. ( 1)

#### DOSAGE AND ADMINISTRATION

- ZEGALOGUE autoinjector and prefilled syringe are for subcutaneous injection only. ( 2.1)
- The dose in adults and pediatric patients aged 6 years and older is 0.6 mg. ( 2.2)
- Administer ZEGALOGUE according to the printed instructions on the protective case label and the Instructions For Use. ( 2.1)
- Visually inspect ZEGALOGUE prior to administration. The solution should appear clear, colorless, and free from particles. If the solution is discolored or contains particulate matter, do not use. ( 2.1)
- Administer the injection into the lower abdomen, buttocks, thigh, or outer upper arm. ( 2.1)
- Call for emergency assistance immediately after administering the dose. ( 2.1)
- If there has been no response after 15 minutes, an additional dose of ZEGALOGUE from a new device may be administered while waiting for emergency assistance. ( 2.1)
- When the patient has responded to treatment, give oral carbohydrates. ( 2.1)
- Do not attempt to reuse ZEGALOGUE. Each device contains a single dose of dasiglucagon and cannot be reused. ( 2.1)

#### DOSAGE FORMS AND STRENGTHS

Injection:

- 0.6 mg/0.6 mL single-dose autoinjector ( 3)
- 0.6 mg/0.6 mL single-dose prefilled syringe ( 3)

#### CONTRAINDICATIONS

Pheochromocytoma ( 4)  
Insulinoma ( 4)

#### WARNINGS AND PRECAUTIONS

- *Substantial Increase in Blood Pressure in Patients with Pheochromocytoma:* Contraindicated in patients

with pheochromocytoma because ZEGALOGUE may stimulate the release of catecholamines from the tumor. ( 4, 5.1)

- *Hypoglycemia in Patients with Insulinoma:* In patients with insulinoma, administration may produce an initial increase in blood glucose, but ZEGALOGUE may stimulate exaggerated insulin release from an insulinoma and cause subsequent hypoglycemia. If a patient develops symptoms of hypoglycemia after a dose of ZEGALOGUE, give glucose orally or intravenously. ( 4, 5.2)
- *Hypersensitivity and Allergic Reactions:* Allergic reactions have been reported with glucagon products and may include generalized rash, and in some cases anaphylactic shock with breathing difficulties and hypotension. ( 5.3)
- *Lack of Efficacy in Patients with Decreased Hepatic Glycogen:* 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 to be effective. Patients with these conditions should be treated with glucose. ( 5.4)

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#### **ADVERSE REACTIONS**

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Most common adverse reactions ( $\geq 2\%$ ) associated with ZEGALOGUE are:

Adults: nausea, vomiting, headache, diarrhea, and injection site pain

Pediatrics: nausea, vomiting, headache, and injection site pain ( 6.1)

**To report SUSPECTED ADVERSE REACTIONS, contact Zealand Pharma A/S at 1-877-501-9342 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

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#### **DRUG INTERACTIONS**

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- *Beta-blockers:* Patients taking beta-blockers may have a transient increase in pulse and blood pressure. ( 7)
- *Indomethacin:* In patients taking indomethacin, ZEGALOGUE may lose its ability to raise blood glucose or may produce hypoglycemia. ( 7)
- *Warfarin:* ZEGALOGUE may increase the anticoagulant effect of warfarin. ( 7)

**See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.**

**Revised: 4/2021**

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## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

ZEGALOGUE<sup>®</sup> is indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above.

### **2 DOSAGE AND ADMINISTRATION**

#### **2.1 Administration Instructions**

ZEGALOGUE autoinjector and prefilled syringe are for subcutaneous injection only.

Instruct patients and their caregivers on the signs and symptoms of severe hypoglycemia. Because severe hypoglycemia requires the help of others to recover, instruct the patient to inform those around them about ZEGALOGUE and its Instructions For Use. Administer ZEGALOGUE as soon as possible when severe hypoglycemia is recognized.

Instruct the patient or caregiver to read the Instructions For Use at the time they receive a prescription for ZEGALOGUE. Emphasize the following instructions to the patient or caregiver:

- Administer ZEGALOGUE according to the printed instructions on the protective case label and the Instructions For Use.
- Visually inspect ZEGALOGUE prior to administration. The solution should appear clear, colorless, and free from particles. If the solution is discolored or contains particulate matter, do not use.
- Administer the injection in the lower abdomen, buttocks, thigh, or outer upper arm.
- Call for emergency assistance immediately after administering the dose.
- If there has been no response after 15 minutes, an additional dose of ZEGALOGUE

may be administered while waiting for emergency assistance.

- When the patient has responded to treatment, give oral carbohydrates to restore liver glycogen and prevent recurrence of hypoglycemia.
- Do not attempt to reuse ZEGALOGUE. Each ZEGALOGUE device contains a single dose of dasiglucagon and cannot be reused.

## **2.2 Recommended Dosage**

The recommended dose of ZEGALOGUE in adults and pediatric patients aged 6 years and older is 0.6 mg administered by subcutaneous injection into the lower abdomen, buttocks, thigh, or outer upper arm.

If there has been no response after 15 minutes, an additional 0.6 mg dose of ZEGALOGUE from a new device may be administered.

## **3 DOSAGE FORMS AND STRENGTHS**

ZEGALOGUE injection is a clear, colorless solution available as:

- 0.6 mg/0.6 mL single-dose autoinjector
- 0.6 mg/0.6 mL single-dose prefilled syringe

## **4 CONTRAINDICATIONS**

ZEGALOGUE is contraindicated in patients with:

- Pheochromocytoma because of the risk of substantial increase in blood pressure [see *Warnings and Precautions (5.1)*]
- Insulinoma because of the risk of hypoglycemia [see *Warnings and Precautions (5.2)*]

## **5 WARNINGS AND PRECAUTIONS**

### **5.1 Substantial Increase in Blood Pressure in Patients with Pheochromocytoma**

ZEGALOGUE is contraindicated in patients with pheochromocytoma because glucagon products may stimulate the release of catecholamines from the tumor [see *Contraindications (4)*]. 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.

### **5.2 Hypoglycemia in Patients with Insulinoma**

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 [see *Contraindications (4)*]. If a patient develops symptoms of hypoglycemia after a dose of ZEGALOGUE, give glucose orally or intravenously.

### **5.3 Hypersensitivity and Allergic Reactions**

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.

#### **5.4 Lack of Efficacy in Patients with Decreased Hepatic Glycogen**

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.

### **6 ADVERSE REACTIONS**

The following important adverse reactions are described elsewhere in the labeling:

- Hypersensitivity and Allergic Reactions [see *Warnings and Precautions (5.3)*]

#### **6.1 Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of ZEGALOGUE cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, 316 adult patients with type 1 diabetes and 20 pediatric patients with type 1 diabetes were exposed to ZEGALOGUE.

The data in Table 1 reflect exposure of 116 adult patients to ZEGALOGUE in 2 placebo-controlled trials (mean age 40 years). Table 2 reflects exposure of 20 pediatric patients exposed to ZEGALOGUE in a placebo-controlled trial. Eight patients were 7 to 11 years old, and 12 were 12 to 17 years old [see *Clinical Studies (14)*].

**Table 1 Adverse Reactions Occurring  $\geq 2\%$  and More Frequently than with Placebo in ZEGALOGUE-treated Adult Patients within 12 hours of Treatment in 2 Placebo-Controlled Trials**

<b>Adverse reaction type</b>	<b>Placebo (N=53)</b>	<b>Dasiglucagon (N=116)</b>
	<b>% of Patients</b>	<b>% of Patients</b>
Nausea	4%	57%
Vomiting	2%	25%
Headache	4%	11%
Diarrhea	0%	5%
Injection site pain	0%	2%

**Table 2 Adverse Reactions Occurring  $\geq 2\%$  and More Frequently than with Placebo in ZEGALOGUE-treated Pediatric Patients within 12 hours of Treatment in a Placebo-Controlled Trial**

<b>Adverse reaction type</b>	<b>Placebo (N=11)</b>	<b>Dasiglucagon Age 6-11 years (N=8)</b>	<b>Dasiglucagon Age 12-17 years (N=12)</b>	<b>Dasiglucagon All (N=20)</b>
	<b>% of Patients</b>	<b>% of Patients</b>	<b>% of Patients</b>	<b>% of Patients</b>
Nausea	0%	25%	92%	65%
Vomiting	0%	25%	67%	50%
Headache	0%	0%	17%	10%
Injection site pain	0%	0%	8%	5%

### Other Adverse Reactions

Other adverse reactions in patients treated with dasiglucagon occurring within 12 hours of treatment include: hypertension, hypotension, bradycardia, presyncope, palpitations, and orthostatic intolerance.

## **6.2 Immunogenicity**

As with all therapeutic peptides, there is a potential for immunogenicity with ZEGALOGUE. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to ZEGALOGUE with the incidence of antibodies to other products may be misleading.

In clinical trials, 4/498 (<1%) of ZEGALOGUE-treated patients developed treatment-emergent anti-drug antibodies (ADAs). Two patients receiving a single dose of ZEGALOGUE had detectable ADAs to dasiglucagon for at least 14 months after dosing. One ADA-positive patient receiving multiple doses of ZEGALOGUE had ADAs with transient neutralizing activity and with cross-reactivity against native glucagon. Although no safety or efficacy concerns were noted for these ADA-positive subjects, it is unknown whether ADAs may affect pharmacokinetics, pharmacodynamics, safety, and/or effectiveness of the drug [see *Clinical Studies (14)*].

## **7 DRUG INTERACTIONS**

**Table 3 Clinically Significant Drug Interactions with ZEGALOGUE**

<b>Beta-Blockers</b>	
<i>Clinical Impact:</i>	Patients taking beta-blockers may have a transient increase in pulse and blood pressure when given ZEGALOGUE.
<b>Indomethacin</b>	
<i>Clinical</i>	In patients taking indomethacin, ZEGALOGUE may

<i>Clinical Impact:</i>	lose its ability to raise blood glucose or may even produce hypoglycemia.
<b>Warfarin</b>	
<i>Clinical Impact:</i>	ZEGALOGUE may increase the anticoagulant effect of warfarin.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

#### Risk Summary

There are no available data on dasiglucagon use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

Untreated hypoglycemia in pregnancy can cause complications and may be fatal.

In animal reproduction studies, daily subcutaneous administration of dasiglucagon to pregnant rabbits and rats during the period of organogenesis did not cause adverse developmental effects at exposures 7 and 709 times the human dose of 0.6 mg based on AUC, respectively (see Data) .

#### Data

##### *Animal Data*

In an embryo-fetal development study, pregnant rats were treated daily with subcutaneous doses of 2, 10, and 24 mg/kg/day during the period of organogenesis (gestation day 6 to 17). Maternal toxicity, in terms of decreased body weight gain, lower fetal body weight, and delayed bone ossification, was observed at  $\geq 10$  mg/kg/day ( $\geq 475$  times the human dose, based on AUC).

In an embryo-fetal development study, pregnant rabbits were treated daily with subcutaneous doses of 0.1, 0.3, and 1 mg/kg/day during the period of organogenesis (gestation day 6 to 19). Lower fetal body weight and delayed bone ossification were observed at 1 mg/kg/day (100 times the human dose, based on AUC), a dose that also induced maternal toxicity in terms of decreased body weight gain. At  $\geq 0.3$  mg/kg/day ( $\geq 20$  times the human dose), dasiglucagon caused fetal skeletal and visceral malformations. No adverse fetal developmental effects were observed at 0.1 mg/kg/day, corresponding to exposure 7 times the human dose.

### 8.2 Lactation

#### Risk Summary

There is no information on the presence of dasiglucagon in either human or animal milk, or the effects of the drug on the breastfed infant or milk production. Dasiglucagon is a peptide and would be expected to be broken down to its constituent amino acids in the infant's digestive tract and is therefore unlikely to cause harm to an exposed infant.

### 8.4 Pediatric Use

The safety and effectiveness of ZEGALOGUE for the treatment of severe hypoglycemia

in patients with diabetes have been established in pediatric patients aged 6 years and above. Use of ZEGALOGUE for this indication is supported by evidence from a study in 42 pediatric patients with type 1 diabetes [see *Clinical Studies (14.2)*].

The safety and effectiveness of ZEGALOGUE have not been established in pediatric patients younger than 6 years of age.

## 8.5 Geriatric Use

Clinical studies of ZEGALOGUE included too few patients 65 years of age and older to determine whether these patients respond differently from younger adult patients.

## 10 OVERDOSAGE

If overdosage occurs, the patient may experience nausea, vomiting, inhibition of GI tract motility, and/or increases in blood pressure and heart rate. In case of suspected overdosing, serum potassium may decrease and should be monitored and corrected if needed. If the patient develops a marked increase in blood pressure, phentolamine mesylate has been shown to be effective in lowering blood pressure for the short time that control would be needed.

Appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms.

## 11 DESCRIPTION

ZEGALOGUE contains dasiglucagon hydrochloride, which is a glucagon analog and an antihypoglycemic agent. Dasiglucagon is comprised of 29 amino acids. The molecular formula of dasiglucagon (anhydrous, free-base) is  $C_{152}H_{222}N_{38}O_{50}$ , and its molecular mass is 3382 g/mol (anhydrous, free-base). Dasiglucagon hydrochloride has the following chemical structure:



ZEGALOGUE injection is a preservative free, sterile, aqueous, clear, and colorless solution for subcutaneous use in a single-dose prefilled syringe and an autoinjector. Each prefilled syringe and autoinjector contains 0.63 mg of dasiglucagon provided as dasiglucagon hydrochloride, which is a salt with 3 - 5 equivalents of hydrochloride, and contains the following inactive ingredients: 3.82 mg tromethamine, 6.44 mg sodium chloride, and water for injection. Hydrochloric acid and/or sodium hydroxide may have been added to adjust pH to 6.5.

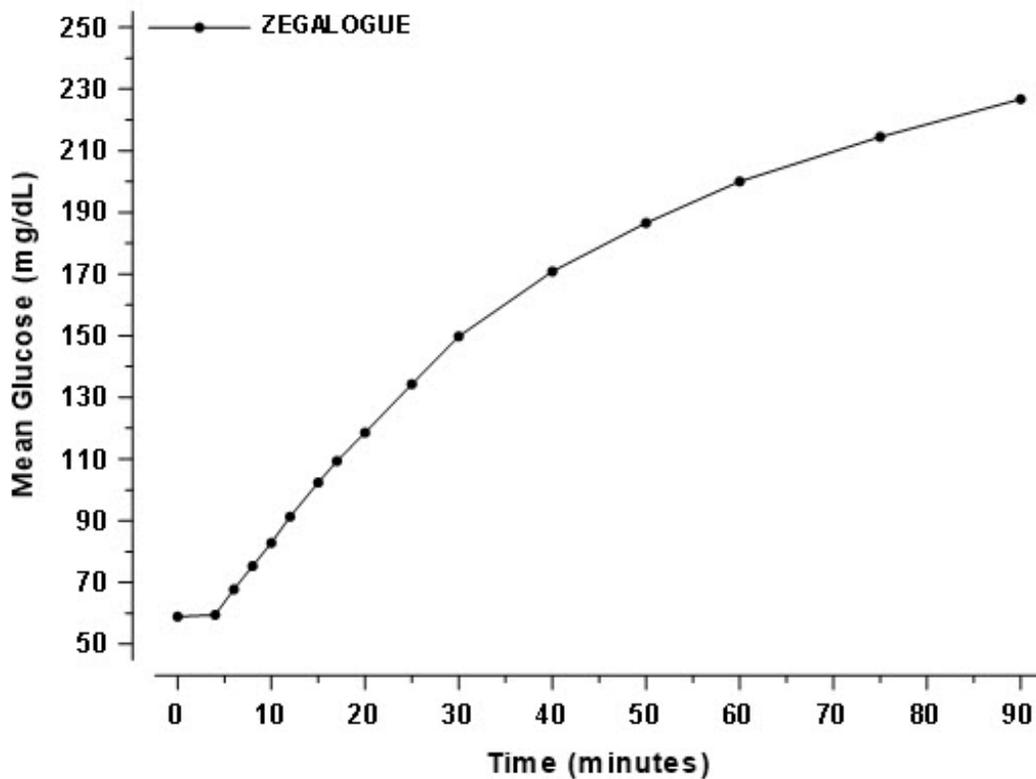
## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

Dasiglucagon is a glucagon receptor agonist, which increases blood glucose concentration by activating hepatic glucagon receptors, thereby stimulating glycogen breakdown and release of glucose from the liver. Hepatic stores of glycogen are necessary for dasiglucagon to produce an antihypoglycemic effect.

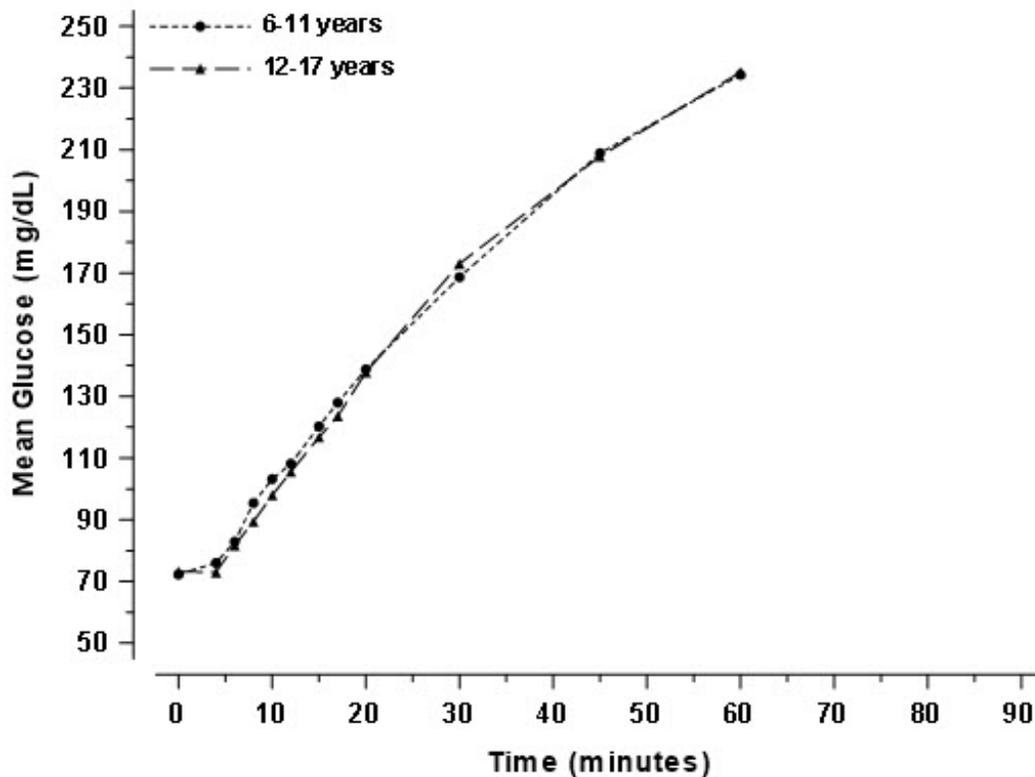
## 12.2 Pharmacodynamics

After administration of ZEGALOGUE in adult patients with type 1 diabetes, the mean glucose increase from baseline at 90 minutes was 168 mg/dL (Figure 1).



**Figure 1 Mean plasma glucose over time in adults with type 1 diabetes administered 0.6 mg dasiglucagon**

In pediatric patients (7 to 17 years) with type 1 diabetes, the mean glucose increase at 60 minutes after administration of ZEGALOGUE was 162 mg/dL (Figure 2).



**Figure 2 Mean plasma glucose over time in pediatric patients with type 1 diabetes administered 0.6 mg dasiglucagon**

#### Cardiac Electrophysiology

At a dose resulting in more than 5 times the concentration achieved with the recommended therapeutic dose, ZEGALOGUE does not prolong the QT interval to any clinically relevant extent.

### **12.3 Pharmacokinetics**

#### Absorption

ZEGALOGUE absorption following subcutaneous injection of 0.6 mg resulted in a mean peak plasma concentration of 5110 pg/mL (1510 pmol/L) at around 35 minutes.

#### Distribution

The mean apparent volume of distribution was 47 L to 57 L following subcutaneous administration.

#### Elimination

The half-life was approximately 30 minutes.

#### *Metabolism*

Metabolism data indicated that dasiglucagon is cleared like native glucagon through proteolytic degradation pathways in blood, liver, and kidney.

#### Specific Populations

After administration of ZEGALOGUE in pediatric patients with type 1 diabetes, the mean peak plasma concentration of 3920 pg/mL occurred at around 21 minutes.

## **13 NONCLINICAL TOXICOLOGY**

### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

#### Carcinogenesis

Long-term studies in animals to evaluate carcinogenicity of dasiglucagon have not been performed.

#### Mutagenesis

Dasiglucagon was not mutagenic or clastogenic in a standard battery of genotoxicity tests: bacterial mutagenicity (Ames), human lymphocyte chromosome aberration, and rat bone marrow micronucleus.

#### Impairment of Fertility

In a fertility and early embryofetal development study in rats, dasiglucagon administered by subcutaneous injection (0.5, 2, and 8 mg/kg/day) did not impair fertility in male and female rats at exposures 179 and 269 times the human dose of 0.6 mg (based on AUC), respectively.

## **14 CLINICAL STUDIES**

Three randomized, double-blind, placebo-controlled, multicenter trials were conducted in patients with type 1 diabetes. Two trials (Trial A and Trial B) were conducted in adult patients, and one trial (Trial C) was conducted in pediatric patients aged 6 to 17 years. In all 3 trials, patients were randomized to ZEGALOGUE 0.6 mg, placebo, or (in Trials A and C) glucagon for injection 1.0 mg. ZEGALOGUE and the comparators were administered as single subcutaneous injections following a controlled induction of hypoglycemia using intravenous administration of insulin. 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 endpoint for all 3 trials was time to plasma glucose recovery (treatment success), defined as an increase in blood glucose of  $\geq 20$  mg/dL from time of administration, 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 timepoints as did Trials A and B, with the exception of the 25, 40, 50, 75 and 90-minute post-treatment timepoints. The primary hypothesis test was superiority of ZEGALOGUE versus placebo. There was no formal hypothesis test of ZEGALOGUE versus glucagon for injection.

### **14.1 Adult Patients**

Trial A, NCT03378635: A total of 170 patients were randomized 2:1:1 to ZEGALOGUE, placebo, and glucagon for injection, stratified by injection sites (abdominal region, buttocks, thigh). The mean age of the patients was 39.1 years (96% were < 65 years), and the mean duration of diabetes was 20.0 years; 63% were male; 92% were White. The mean baseline plasma glucose was 58.8 mg/dL. The median time to plasma glucose recovery was statistically significantly shorter for ZEGALOGUE (10 minutes) versus placebo (40 minutes) (Table 4). Figure 3 shows the cumulative proportions of patients

achieving plasma glucose recovery over time. The median time to plasma glucose recovery was numerically similar between ZEGALOGUE (10 minutes) and glucagon for injection (12 minutes).

Trial B, NCT03688711: A total of 45 patients were randomized 3:1 to ZEGALOGUE and placebo stratified by injection sites (buttocks, deltoid). The mean age of the patients was 41.0 years (95% were < 65 years), and the mean duration of diabetes was 22.5 years; 57% were male; 93% were White. The mean baseline plasma glucose was 55.0 mg/dL. The median time to plasma glucose recovery was statistically significantly shorter for ZEGALOGUE (10 minutes) versus placebo (35 minutes) (Table 4).

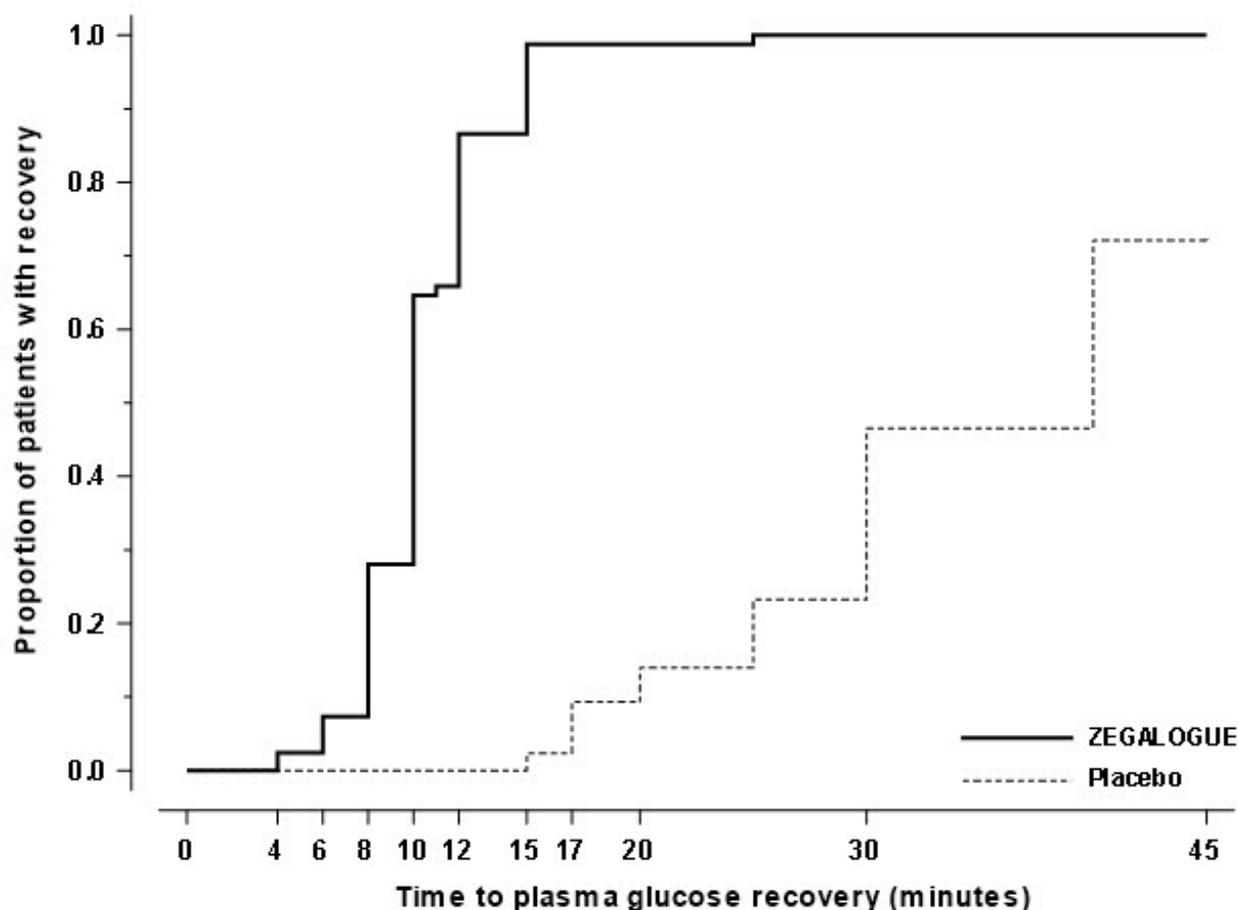
**Table 4 Plasma Glucose Recovery in Adult Patients**

	Trial A		Trial B	
	ZEGALOGUE N=82	Placebo N=43	ZEGALOGUE N=34	Placebo N=10
<b>Median time to recovery [95% CI*]</b>	10 min [10; 10] †	40 min [30; 40]	10 min [8; 12] †	35 min [20; -)

N is the number of patients who were randomized and treated.

\* log-log confidence interval

† p < 0.001 versus placebo (log-rank test stratified by injection sites)



**Figure 3 Time to plasma glucose recovery in Trial A**

## 14.2 Pediatric Patients

Trial C, NCT03667053: Pediatric patients aged 6 to 17 years and weighing  $\geq 20$  kg, were randomized 2:1:1 to ZEGALOGUE, placebo, and glucagon for injection, stratified by injection sites (abdominal region, thigh) and age groups (6-11 years and 12-17 years). A total of 42 patients were randomized. The mean age was 12.5 years (range 7 to 17 years), and the mean duration of diabetes was 5.9 years; 56% were male; 95% were White. The mean baseline plasma glucose was 72.0 mg/dL. The median time to plasma glucose recovery was statistically significantly shorter for ZEGALOGUE (10 minutes) versus placebo (30 minutes) (Table 5). Figure 4 shows the cumulative proportions of pediatric patients achieving plasma glucose recovery over time. The median time to plasma glucose recovery was numerically similar between ZEGALOGUE (10 minutes) and glucagon for injection (10 minutes).

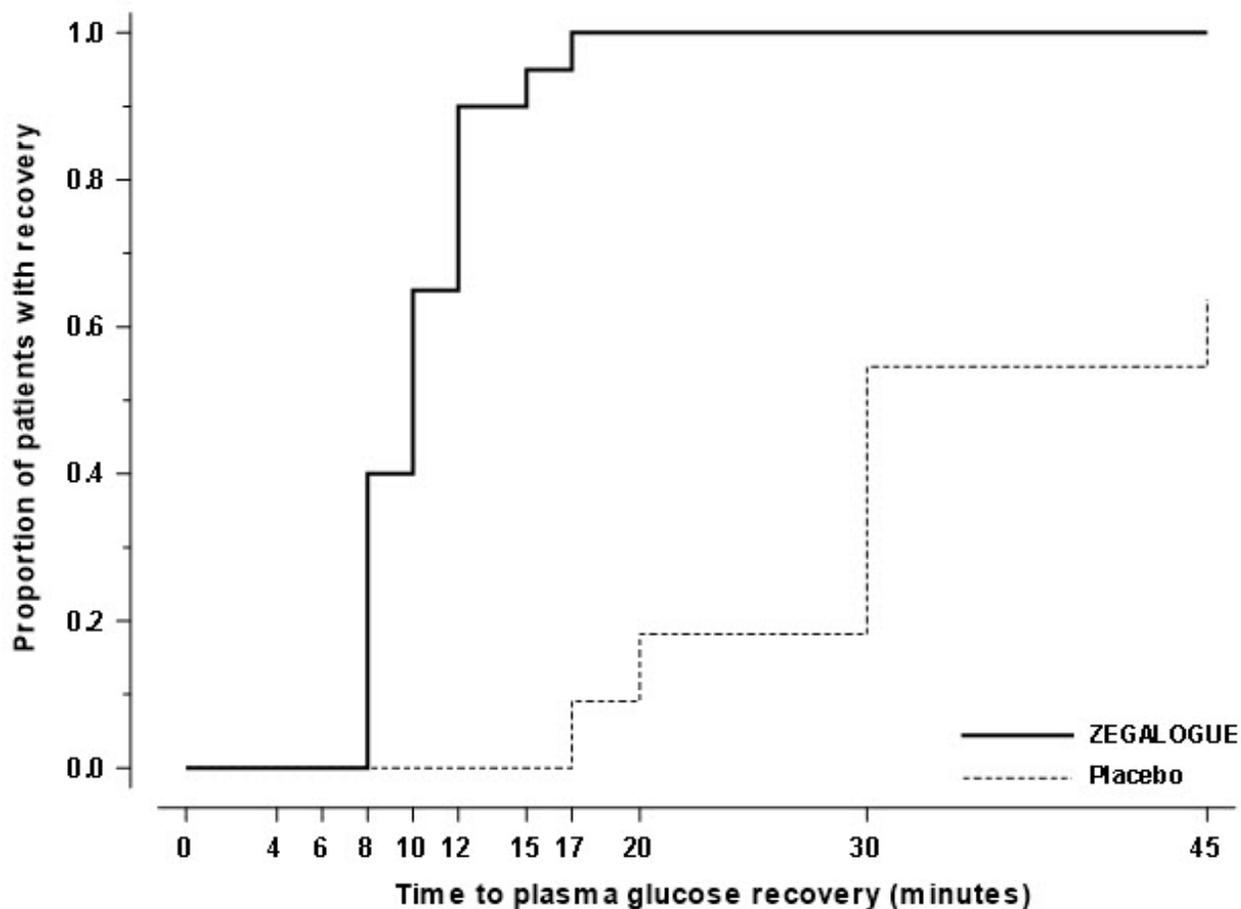
**Table 5 Plasma Glucose Recovery in Pediatric Patients**

	Trial C	
	ZEGALOGUE N=20	Placebo N=11
<b>Median time to recovery [95% CI *]</b>	10 min [8; 12] †	30 min [20; -)

N is the number of patients who were randomized and treated.

\* log-log confidence interval

†  $p < 0.001$  versus placebo (log-rank test stratified by injection site and age group)



**Figure 4 Time to plasma glucose recovery in Trial C**

## 16 HOW SUPPLIED/STORAGE AND HANDLING

### 16.1 How Supplied

ZEGALOGUE injection is a clear, colorless solution supplied as follows:

Presentation	Strength	Package Size	NDC
Single-dose autoinjector	0.6 mg/0.6 mL	1	80644-0012-1
Single-dose autoinjector	0.6 mg/0.6 mL	2	80644-0012-2
Single-dose prefilled syringe	0.6 mg/0.6 mL	1	80644-0013-1
Single-dose prefilled syringe	0.6 mg/0.6 mL	2	80644-0013-2

### 16.2 Recommended Storage

Store ZEGALOGUE in a refrigerator, 2°C to 8°C (36°F to 46°F). Keep away from the cooling element. Do not freeze.

ZEGALOGUE can be kept at room temperature between 20°C to 25°C (68°F to 77°F) for

up to 12 months. Record the date when the product was removed from the refrigerator in the space provided on the protective case. Do not return the product to the refrigerator after storing at room temperature. Store in the provided protective case and protect from light.

Discard ZEGALOGUE after the end of the 12-month period at room temperature storage, or after the expiration date stated on the product, whichever occurs first.

The inside of the gray cap on ZEGALOGUE autoinjector contains dry natural rubber (a derivative of latex).

The inside of the gray needle cover on ZEGALOGUE prefilled syringe contains dry natural rubber (a derivative of latex).

## **17 PATIENT COUNSELING INFORMATION**

Advise the patient and family members or caregivers to read the FDA-approved patient labeling (Patient Information and Instructions For Use).

### Recognition of Severe Hypoglycemia

Inform patient and family members or caregivers on how to recognize the signs and symptoms of severe hypoglycemia and the risks of prolonged hypoglycemia.

### Administration

Review the Patient Information and Instructions For Use with the patient and family members or caregivers.

### Serious Hypersensitivity

Inform patients that allergic reactions can occur with glucagon products like ZEGALOGUE. Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions [see *Warnings and Precautions (5.3)*].

Manufactured for:  
Zealand Pharma A/S  
2860 Søborg, Denmark

Manufactured by:  
Rechon Lifescience AB  
Malmö, Sweden

<p style="text-align: center;"><b>Patient Information</b> <b>ZEGALOGUE (ze' gah log)</b> <b>(dasiglucagon) injection, for subcutaneous use</b></p>
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<p><b>What is ZEGALOGUE?</b></p>
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<p>ZEGALOGUE is a prescription medicine used to treat very low blood sugar (severe hypoglycemia) in people with diabetes aged 6 years and older. It is not known if ZEGALOGUE is safe and effective in children under 6 years of age.</p>
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<p><b>Do not use ZEGALOGUE if you:</b></p>
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- |  |
|--|
| <ul style="list-style-type: none"><li>• have a tumor called pheochromocytoma in the gland on top of your kidneys (adrenal gland).</li><li>• have a tumor called insulinoma in your pancreas.</li></ul> |
|--|

**Before using ZEGALOGUE, tell your healthcare provider about all of your medical conditions, including if you:**

- have a tumor in your pancreas.
- are allergic to dasiglucagon or any other ingredients in ZEGALOGUE. See the end of this Patient Information for a complete list of ingredients in ZEGALOGUE.
- have not had food or water for a long time (prolonged fasting or starvation).
- have adrenal insufficiency.
- have low blood sugar that does not go away (chronic hypoglycemia).
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if ZEGALOGUE passes into your breast milk. You and your healthcare provider should decide if you can use ZEGALOGUE while breastfeeding.

**Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.**

**How should I use ZEGALOGUE?**

- Read the detailed Instructions For Use that come with ZEGALOGUE.
- Use ZEGALOGUE exactly how your healthcare provider tells you to use it.
- Make sure your caregiver knows where you keep your ZEGALOGUE and how to use ZEGALOGUE the right way before you need it.
- Your caregiver must act quickly. Having very low blood sugar for a period of time may be harmful.
- Your healthcare provider will tell you how and when to use ZEGALOGUE.
- **After giving ZEGALOGUE, your caregiver should call for emergency medical help right away.**
- Once you are able to safely consume food or drink, your caregiver should give you a fast-acting source of sugar (such as fruit juice) and a long-acting source of sugar (such as crackers with cheese or peanut butter).
- If you do not respond to treatment after 15 minutes, your caregiver may give you another dose, if available.
- Tell your healthcare provider each time you use ZEGALOGUE. Your healthcare provider may need to change the dose of your other diabetes medicines.

**What are the possible side effects of ZEGALOGUE?**

**ZEGALOGUE may cause serious side effects, including:**

- **high blood pressure.** ZEGALOGUE can cause high blood pressure in certain people with tumors in their adrenal glands.
- **low blood sugar.** ZEGALOGUE can cause certain people with tumors in their pancreas called insulinomas to have low blood sugar.
- **serious allergic reaction.** Call your healthcare provider or **get medical help right away** if you have a serious allergic reaction including: rash, difficulty breathing, or low blood pressure (hypotension).

**The most common side effects of ZEGALOGUE include:**

- |                  |                    |
|------------------|--------------------|
| 1. <b>Adults</b> | 1. <b>Children</b> |
| 2. nausea        | 2. nausea          |
| 3. vomiting      | 3. vomiting        |
| 4. headache      | 4. headache        |

5. diarrhea
6. injection site pain

4. headache
5. injection site pain

These are not all of the possible side effects of ZEGALOGUE. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store ZEGALOGUE?**

- Store ZEGALOGUE in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Do not freeze ZEGALOGUE.
- ZEGALOGUE can also be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 12 months. See example in the Instructions For Use for how to keep track of this 12-month period.
- Do not return ZEGALOGUE to the refrigerator after storing at room temperature.
- Throw away ZEGALOGUE if it has been stored at room temperature for more than 12 months.
- Replace ZEGALOGUE before the expiration date printed on the red protective case.
- Store ZEGALOGUE in the red protective case it comes in.

#### **Keep ZEGALOGUE and all medicines out of the reach of children.**

#### **General information about the safe use of ZEGALOGUE.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ZEGALOGUE for a condition for which it was not prescribed. Do not give ZEGALOGUE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ZEGALOGUE that is written for healthcare professionals.

#### **What are the ingredients in ZEGALOGUE?**

**Active ingredient:** dasiglucagon, provided as dasiglucagon hydrochloride

**Inactive ingredients:** tromethamine, sodium chloride and water for injection.

Hydrochloric acid and/or sodium hydroxide may be added to adjust pH

Manufactured for: Zealand Pharma A/S, 2860 Søborg, Denmark by Rechon Lifescience AB, Malmö, Sweden

For more information go to [www.zegalogue.com](http://www.zegalogue.com) or call 1-877-501-9342 .

This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued:04/2021

## **INSTRUCTIONS FOR USE**

**ZEGALOGUE<sup>®</sup> (ze' gah log)  
(dasiglucagon) injection**

**0.6 mg/0.6 mL**

**Emergency Use for Very Low Blood Sugar**

**Single-Dose**

**Prefilled Syringe**

**Injection, for subcutaneous use**

**Important: ZEGALOGUE is used to treat very low blood sugar (severe hypoglycemia) where you need help from others.**

ZEGALOGUE contains 1 dose of dasiglucagon in a prefilled syringe and cannot be reused.

**Read and understand this Instructions For Use before an emergency happens.**

Show your family and friends where you keep ZEGALOGUE and explain how to use it by sharing these instructions, so they know how to use ZEGALOGUE before an emergency happens.

The inside of the gray needle cover contains dry natural rubber, which may cause allergic reactions in people with latex allergy.

**Read before Injecting ZEGALOGUE**

---

- **Do not** use ZEGALOGUE if the:
  - **expiration date has passed**
  - **gray needle cover is missing or**
  - **syringe appears damaged**
- When opening the red protective case make sure to hold it up straight (with the gray cap on top) to avoid dropping ZEGALOGUE.
- **Do not** remove the gray needle cover until you are ready to inject ZEGALOGUE.
- For questions or more information about ZEGALOGUE, call your healthcare provider.

**Storage information**

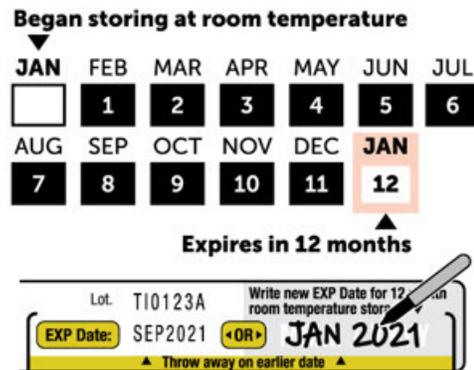
---

- **Store ZEGALOGUE in the refrigerator between 36°F to 46°F (2°C to 8°C).**
- **Do not** freeze.
- Store ZEGALOGUE in the red protective case it comes in.
- ZEGALOGUE can also be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 12 months. See example to the right for how to keep track of this 12-month period.
- **Do not** return to refrigerator after storing at room temperature.
- Throw away ZEGALOGUE if it has been stored at room temperature for more than 12 months.
- Replace ZEGALOGUE before the expiration date printed on the red protective case.
- **Keep ZEGALOGUE and all medicines out of the reach of children.**

If ZEGALOGUE is removed from the refrigerator to be stored at room temperature, write down the new 12-month expiration date on the label found on the red protective case.



**For example:** If ZEGALOGUE was removed from refrigerator to be stored at room temperature in January 2020, then write the new expiration date of January 2021 on the label.



**Note:** ZEGALOGUE will expire on the earlier of the two expiration dates.

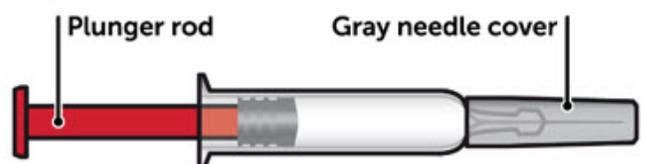
## Description of parts

### Red protective case



### ZEGALOGUE®

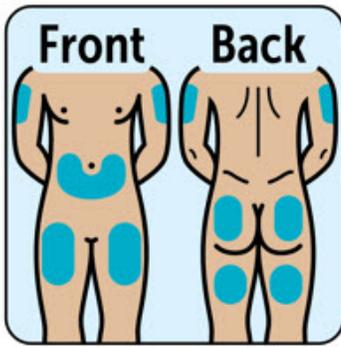
#### Prefilled Syringe



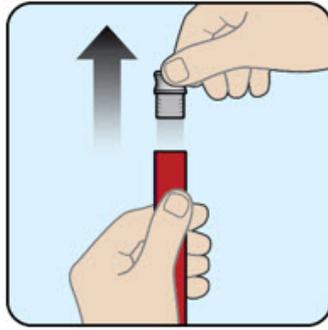
## Before injection

Choose injection site and expose skin

Hold the red protective case



**upright and  
remove gray cap**



Injection sites include:

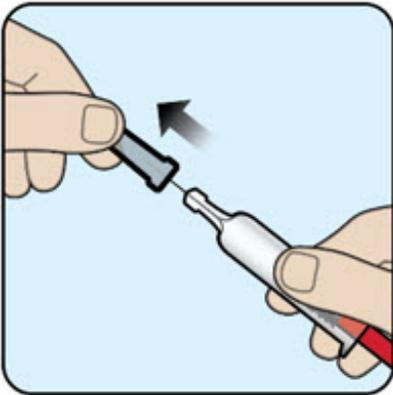
- **Outer upper arms**
  - **Lower abdomen**  
(at least 2 inches from the belly button)
  - **Front or back of thighs**
  - **Buttocks**
- Hold the red protective case upright with the gray cap on top.
  - Pull the gray cap up to open.
  - Carefully remove ZEGALOGUE from the red protective case without dropping it.

Roll back any clothing to expose bare skin.  
**Do not** inject through clothes.

## How to inject

### Step 1

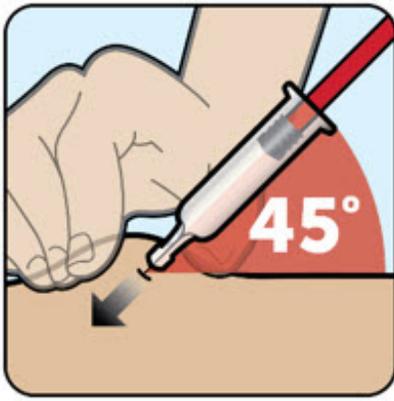
**Remove the gray needle cover**



Pull the gray needle cover straight off. Be careful not to bend the needle.

### Step 2

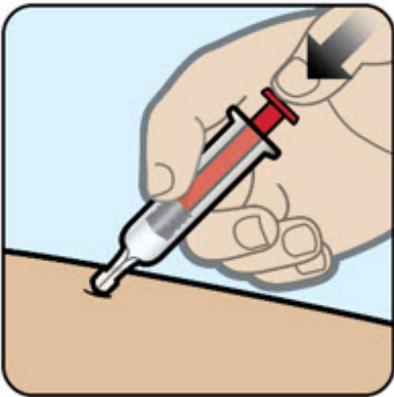
**Pinch the skin and insert the needle**



Gently pinch the skin and insert the entire needle into the skin at a 45° angle.

### **Step 3**

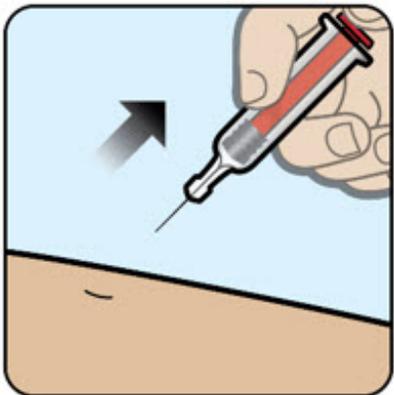
#### **Give the injection**



After inserting the needle, release the pinched skin and slowly press the plunger rod all the way down until the syringe is empty and the plunger rod stops.

### **Step 4**

#### **Remove the needle**



After the plunger rod stops and the injection is complete, carefully remove the needle from the injection site.

### **After injection**

- After you have given the injection, roll the unconscious person on to their side to prevent choking.
- **Call for emergency medical help or a healthcare provider right away after you have injected ZEGALOGUE.** Even if the ZEGALOGUE injection helps the person to wake up, still call for emergency medical help right away. If the person does not respond after 15 minutes, another dose may be given, if available.

- Once the person is able to safely consume food or drink, give the person a fast-acting source of sugar (such as fruit juice) and a long-acting source of sugar (such as crackers with cheese or peanut butter).
- **Replace the used ZEGALOGUE right away so you will have a new ZEGALOGUE in case you need it.**

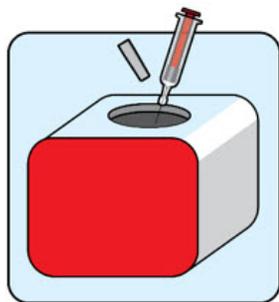
## **Hypoglycemia may happen again after receiving ZEGALOGUE treatment.**

### **Early symptoms of hypoglycemia may include:**

- sweating
- drowsiness
- dizziness
- sleep disturbances
- irregular heartbeat (palpitation)
- anxiety
- tremor
- blurred vision
- hunger
- slurred speech
- restlessness
- depressed mood
- tingling in the hands, feet, lips, or tongue
- irritability
- abnormal behavior
- lightheadedness
- unsteady movement
- inability to concentrate
- personality changes
- headache

If not treated early, hypoglycemia may worsen and the person may have severe hypoglycemia. Signs of severe hypoglycemia include confusion, seizures, unconsciousness, and death.

## **How to throw away (dispose of) ZEGALOGUE**



**Put your expired or used needles and syringes in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.**

**If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:**

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

Dispose of your ZEGALOGUE and the gray needle cover in an FDA-cleared sharps disposal container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the correct way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>

**Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit it.  
**Do not** recycle your used sharps disposal container.

This Instructions For Use has been approved by the U.S. Food and Drug Administration.

Manufactured for:  
Zealand Pharma A/S  
Sydmarken 11  
2860 Søborg, Denmark

Manufactured by:  
Rechon Lifescience AB  
Malmö, Sweden

REP-5121-C22  
Revised 04/2021

## **INSTRUCTIONS FOR USE**

**ZEGALOGUE<sup>®</sup> (ze' gah log)  
(dasiglucagon) injection**

**0.6 mg/0.6 mL**

**Emergency Use for Very Low Blood Sugar  
Single-Dose  
Autoinjector  
Injection, for subcutaneous use**

**Important: ZEGALOGUE is used to treat very low blood sugar (severe hypoglycemia) where you need help from others.**

ZEGALOGUE contains 1 dose of dasiglucagon in a prefilled autoinjector and cannot be reused.

**Read and understand this Instructions For Use before an emergency happens.**

Show your family and friends where you keep ZEGALOGUE and explain how to use it by sharing these instructions, so they know how to use ZEGALOGUE before an emergency happens.

The inside of the gray cap contains dry natural rubber, which may cause allergic reactions in people with latex allergy.

### **Read before injecting ZEGALOGUE**

---

- **Do not** use ZEGALOGUE if the:
  - **expiration date has passed**
  - **gray cap is missing or**
  - **autoinjector appears damaged**
- When opening the red protective case make sure to hold it up straight (with the gray lid on top) to avoid dropping ZEGALOGUE.

- **Do not** remove the gray cap until you are ready to inject ZEGALOGUE.
- For questions or more information about ZEGALOGUE, call your healthcare provider.

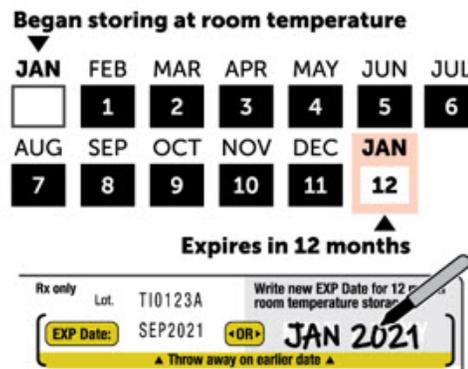
## Storage information

- **Store ZEGALOGUE in the refrigerator between 36°F to 46°F (2°C to 8°C).**
- **Do not** freeze.
- Store ZEGALOGUE in the red protective case it comes in.
- ZEGALOGUE can also be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 12 months. See example to the right for how to keep track of this 12-month period.
- **Do not** return to refrigerator after storing at room temperature.
- Throw away ZEGALOGUE if it has been stored at room temperature for more than 12 months.
- Replace ZEGALOGUE before the expiration date printed on the red protective case.
- **Keep ZEGALOGUE and all medicines out of the reach of children.**

If ZEGALOGUE is removed from the refrigerator to be stored at room temperature, write down the new 12-month expiration date on the label found on the red protective case.



**For example:** If ZEGALOGUE was removed from the refrigerator to be stored at room temperature in January 2020, then write the new expiration date of January 2021 on the label.



**Note:** ZEGALOGUE will expire on the earlier of the two expiration dates.

## Description of parts

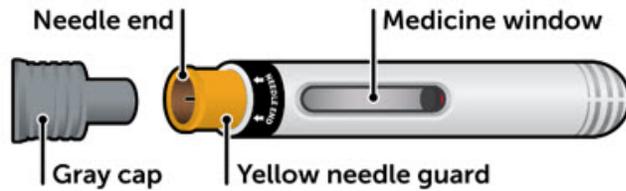
### Red protective case



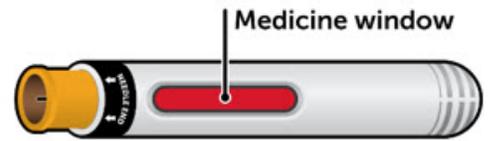
# ZEGALOGUE

## Autoinjector

### Before injection

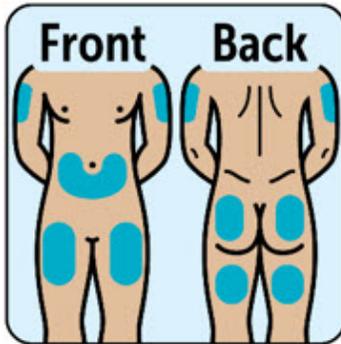


### After injection

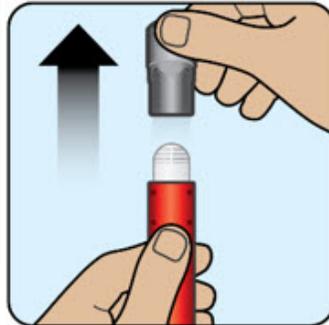


### Before injection

Choose injection site and expose skin



Hold the red protective case upright and remove gray lid



Injection sites include:

- **Outer upper arms**
  - **Lower abdomen** (at least 2 inches from the belly button)
  - **Front or back of thighs**
  - **Buttocks**
- Hold the red protective case upright with the gray lid on top.
  - Pull the gray lid up to open.
  - Carefully remove ZEGALOGUE from the red protective case without dropping it.

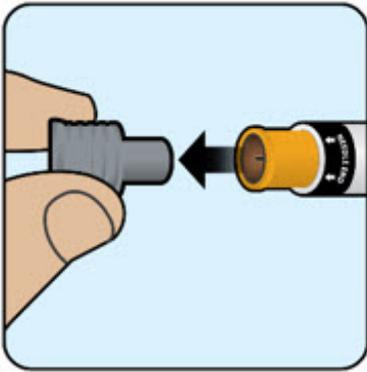
Roll back any clothing to expose bare skin.

**Do not** inject through clothes.

### How to inject

#### Step 1

**Remove the gray cap from needle end**

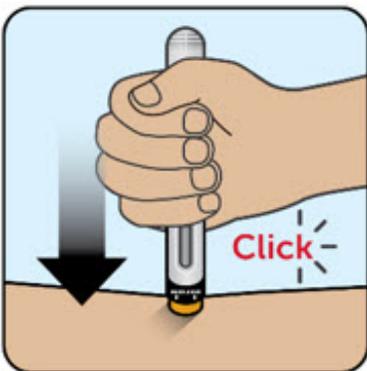


Pull the gray cap straight off.

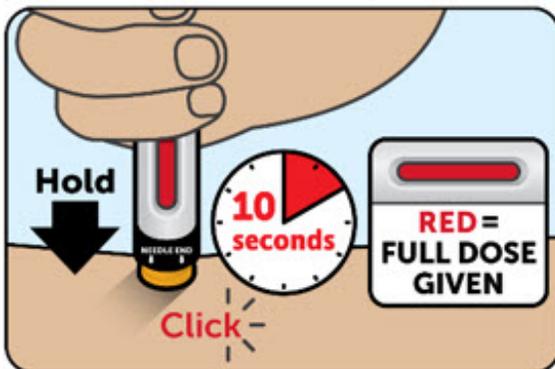
**Do not** put your hand or fingers anywhere near the yellow needle guard. Touching the yellow needle guard may cause an accidental needle stick injury.

### Step 2

**Push and hold down ZEGALOGUE for 10 seconds and check window is red**



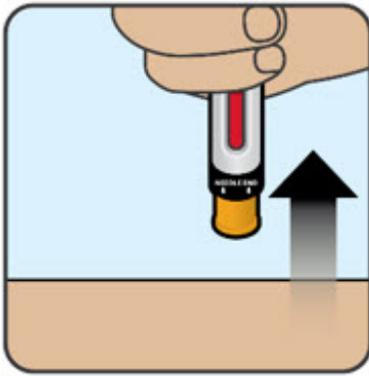
**Push ZEGALOGUE straight down** on skin until the yellow needle guard is fully pressed down. You may hear the first click.



**Keep holding ZEGALOGUE down and slowly count to 10 seconds.** During this time the **medicine window will turn red** and you may hear a second click. Check that the medicine window is red, which means that the full dose has been given.

### Step 3

**Remove ZEGALOGUE from injection site**



Remove ZEGALOGUE by lifting it straight up. The yellow needle guard will cover the needle and lock, preventing an accidental needle stick injury.

### **After injection**

---

- After you have given the injection, roll the unconscious person on to their side to prevent choking.
- **Call for emergency medical help or a healthcare provider right away after you have injected ZEGALOGUE.** Even if the ZEGALOGUE injection helps the person to wake up, still call for emergency medical help right away. If the person does not respond after 15 minutes, another dose may be given, if available.
- Once the person is able to safely consume food or drink, give the person a fast-acting source of sugar (such as fruit juice) and a long-acting source of sugar (such as crackers with cheese or peanut butter).
- **Replace the used ZEGALOGUE right away so you will have a new ZEGALOGUE in case you need it.**

**Hypoglycemia may happen again after receiving ZEGALOGUE treatment.**

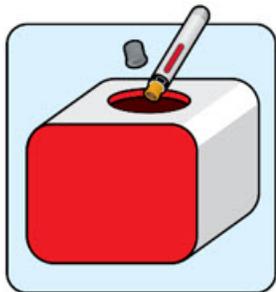
**Early symptoms of hypoglycemia may include:**

- sweating
- drowsiness
- dizziness
- sleep disturbances
- irregular heartbeat (palpitation)
- anxiety
- tremor
- blurred vision
- hunger
- slurred speech
- restlessness
- depressed mood
- tingling in the hands, feet, lips, or tongue
- irritability
- abnormal behavior
- lightheadedness
- unsteady movement
- inability to concentrate
- personality changes
- headache

If not treated early, hypoglycemia may worsen and the person may have severe hypoglycemia. Signs of severe hypoglycemia include confusion, seizures, unconsciousness, and death.

## How to throw away (dispose of) ZEGALOGUE

**Put your expired or used ZEGALOGUE in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) autoinjectors, loose needles and syringes in your household trash.**



**If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:**

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

Dispose of your ZEGALOGUE and gray cap in an FDA-cleared sharps disposal container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the correct way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used autoinjectors. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>

**Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit it.

**Do not** recycle your used sharps disposal container.

This Instructions For Use has been approved by the U.S. Food and Drug Administration.

Manufactured for:  
Zealand Pharma A/S  
Sydmarken 11  
2860 Søborg, Denmark

Manufactured by:  
Rechon Lifescience AB  
Malmö, Sweden

REP-5122-C23  
Revised 04/2021

### **PRINCIPAL DISPLAY PANEL - 0.6 mg/0.6 mL Prefilled Syringe Carton**

Emergency Use for Very Low Blood Sugar

ZEGALOGUE<sup>®</sup>  
(dasiglucagon) injection  
0.6 mg/0.6 mL\*  
Prefilled Syringe

Single-Dose

Injection, for subcutaneous use. Rx only  
NDC 80644-0013-1

Carton contents:  
1 Single-Dose Prefilled Syringe  
1 Prescribing Information

OPEN HERE

ZEALAND PHARMA



## PRINCIPAL DISPLAY PANEL - 0.6 mg/0.6 mL Autoinjector Carton

Emergency Use for Very Low Blood Sugar

ZEGALOGUE®  
(dasiglucagon) injection  
0.6 mg/0.6 mL\*  
Autoinjector

Single-Dose

Injection, for subcutaneous use. Rx only  
NDC 80644-0012-1

Carton contents:  
1 Single-Dose Autoinjector  
1 Prescribing Information

OPEN HERE

ZEALAND PHARMA



## ZEGALOGUE

dasiglucagon injection, solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:80644-0013
<b>Route of Administration</b>	SUBCUTANEOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DASIGLUCAGON</b> (UNII: AD4J2O47FQ) (DASIGLUCAGON - UNII:AD4J2O47FQ)	DASIGLUCAGON	0.6 mg in 0.6 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>TROMETHAMINE</b> (UNII: 023C2WHX2V)	3.82 mg in 0.6 mL
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	6.44 mg in 0.6 mL
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80644-	1 in 1 PACKAGE	04/05/2021	

1	0013-1	1 in 1 PACKAGE	04/05/2021	
1		1 in 1 CONTAINER		
1		0.6 mL in 1 SYRINGE, GLASS; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:80644-0013-2	2 in 1 CARTON	04/05/2021	
2		1 in 1 PACKAGE		
2		1 in 1 CONTAINER		
2		0.6 mL in 1 SYRINGE, GLASS; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA214231	04/05/2021	

## ZEGALOGUE

dasiglucagon injection, solution

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:80644-0012
Route of Administration	SUBCUTANEOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DASIGLUCAGON (UNII: AD4J2O47FQ) (DASIGLUCAGON - UNII:AD4J2O47FQ)	DASIGLUCAGON	0.6 mg in 0.6 mL

### Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TROMETHAMINE (UNII: 023C2WHX2V)	3.82 mg in 0.6 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	6.44 mg in 0.6 mL
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80644-0012-1	1 in 1 PACKAGE	04/05/2021	
1		1 in 1 CONTAINER		
1		0.6 mL in 1 SYRINGE, GLASS; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

2	NDC:80044-0012-2	2 in 1 CARTON	04/05/2021	
2		1 in 1 PACKAGE		
2		1 in 1 CONTAINER		
2		0.6 mL in 1 SYRINGE, GLASS; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA214231	04/05/2021	

**Labeler** - Zealand Pharma US, Inc (117052161)

Revised: 12/2024

Zealand Pharma US, Inc