

INSTRUCTIONS FOR USE

ZEGALOGUE® (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.

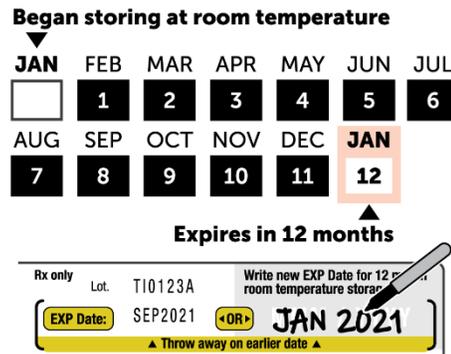
Storage information

- 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

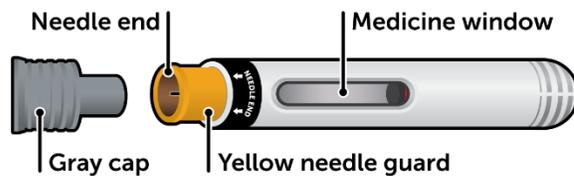
Red protective case



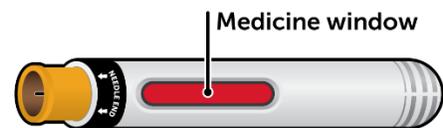
ZEGALOGUE

Autoinjector

Before injection

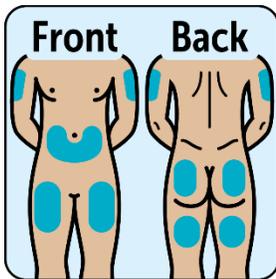


After injection



Before injection

Choose injection site and expose skin

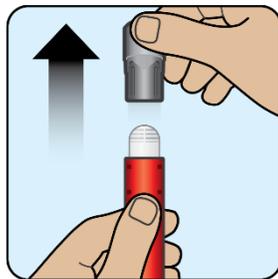


Injection sites include:

- **Outer upper arms**
- **Lower abdomen**
(at least 2 inches from the belly button)
- **Front or back of thighs**
- **Buttocks**

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

Hold the red protective case upright and remove gray lid

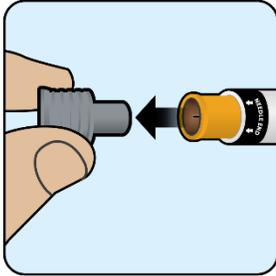


- Hold the red protective case upright with the gray lid on top.
- Pull the gray lid up to open.
- Carefully remove ZEGALOGUE from the red protective case without dropping it.

How to inject

Step 1

Remove the gray cap from needle end

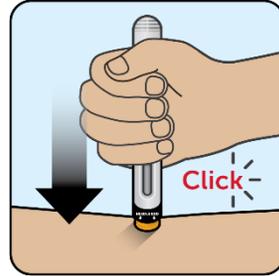


Pull the gray cap straight off.

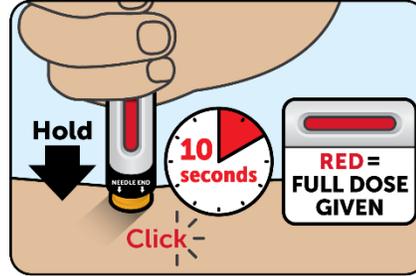
Do not put your hand or fingers anywhere near the yellow needle guard. Touching the yellow needle guard may cause an accidental needle stick injury.

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.

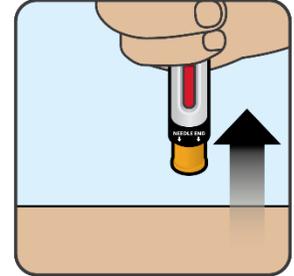


Keep holding ZEGALOGUE down and slowly count to 10 seconds. During this time the **medicine window will turn red** and you may hear a second click.

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.**

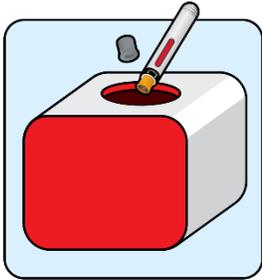
Hypoglycemia may happen again after receiving ZEGALOGUE treatment.

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



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

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

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 Life Science AB, Malmö, Sweden

Rev 1
Revised 04/2021