

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ogluo 0.5 mg solution for injection in pre-filled pen.

Ogluo 1 mg solution for injection in pre-filled pen.

Ogluo 0.5 mg solution for injection in pre-filled syringe.

Ogluo 1 mg solution for injection in pre-filled syringe.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ogluo 0.5 mg solution for injection in pre-filled pen

Each pre-filled pen contains 0.5 mg glucagon in 0.1 mL.

Ogluo 1 mg solution for injection in pre-filled pen

Each pre-filled pen contains 1 mg glucagon in 0.2 mL.

Ogluo 0.5 mg solution for injection in pre-filled syringe

Each pre-filled syringe contains 0.5 mg glucagon in 0.1 mL.

Ogluo 1 mg solution for injection in pre-filled syringe

Each pre-filled syringe contains 1 mg glucagon in 0.2 mL.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection (injection)

A clear, colourless to pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ogluo is indicated for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus.

4.2 Posology and method of administration

Posology

Adults and adolescents (≥ 6 years)

The recommended dose is 1 mg, administered by subcutaneous injection.

Paediatric population (≥ 2 to < 6 years)

- The recommended dose for paediatric patients who weigh less than 25 kg is 0.5 mg administered by subcutaneous injection.
- The recommended dose for paediatric patients who weigh 25 kg or greater is 1 mg administered by subcutaneous injection.

Time to respond and additional doses

The patient will normally respond within 15 minutes. When the patient has responded to the treatment, give an oral carbohydrate to restore the liver glycogen and prevent relapse of hypoglycaemia. If the patient does not respond within 15 minutes, an additional dose of Ogluo from a new device may be administered while waiting for emergency assistance. It is recommended that patients are prescribed two Ogluo devices.

Special populations

Elderly (≥ 65 years old)

Ogluo can be used in elderly patients. No dose adjustment is required.

Efficacy and safety data are very limited in patients aged 65 years and absent in patients aged 75 and above.

Renal impairment

Ogluo can be used in patients with renal impairment. No dose adjustment is required.

Hepatic impairment

Ogluo can be used in patients with hepatic impairment. No dose adjustment is required.

Paediatric population (<2 years)

The safety and efficacy of Ogluo in children aged less than 2 years have not been established. No data are available.

Method of administration

Ogluo pre-filled pen and pre-filled syringe are for subcutaneous injection only.

Patients and their caregivers should be instructed on the signs and symptoms of severe hypoglycaemia. As severe hypoglycaemia requires the help of others to recover, the patient should be instructed to inform those around them about Ogluo and its package leaflet. Ogluo should be administered as soon as possible when severe hypoglycaemia is recognised.

The patient or caregiver should be instructed to read the package leaflet at the time they receive a prescription for Ogluo. The following instructions should be emphasised:

- The foil pouch should not be opened until glucagon needs to be administered.
- The medicinal product should be administered according to the printed instructions on the foil pouch label, carton, or the package leaflet.
- The solution should be visually inspected prior to administration. The solution should appear clear and colourless to pale yellow and be free of particles. If the solution is discoloured or contains particulate matter, the medicinal product should not be used.
- Any clothing covering the injection site should be removed. The injection should be administered in the lower abdomen, outer thigh, or outer upper arm.
- Emergency assistance should be called immediately after administering the dose, even if the patient is not unconscious.
- Each device contains a single dose of glucagon and cannot be reused.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Pheochromocytoma.

4.4 Special warnings and precautions for use

Glycogen stores and hypoglycaemia

To prevent relapse of the hypoglycaemia, oral carbohydrates should be given to restore the liver glycogen, when the patient has responded to the treatment.

Glucagon will not be effective in patients whose liver glycogen is depleted. For that reason, glucagon has little or no effect when the patient has been fasting for a prolonged period, or is suffering from adrenal insufficiency, chronic hypoglycaemia, or alcohol induced hypoglycaemia.

Glucagon, unlike adrenaline, has no effect upon muscle phosphorylase and therefore cannot assist in the transference of carbohydrate from the much larger stores of glycogen that are present in the skeletal muscle.

Insulinoma

In patients with insulinoma, administration of glucagon may produce an initial increase in blood glucose. However, glucagon administration may directly or indirectly (through an initial rise in blood glucose) stimulate exaggerated insulin release from an insulinoma and cause hypoglycaemia. A patient developing symptoms of hypoglycaemia after a dose of glucagon should be given glucose orally or intravenously.

Caution should also be observed in patients with glucagonoma.

Recovery time

Please take into account that approximately 15% of patients achieved glucose recovery after 20 minutes or more in the pivotal trial.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Insulin

Insulin reacts antagonistically towards glucagon.

Indomethacin

When used with indomethacin, glucagon may lose its ability to raise blood glucose or paradoxically, may even produce hypoglycaemia.

Warfarin

Glucagon may increase the anticoagulant effect of warfarin.

Beta-blockers

Patients taking beta-blockers might be expected to have a greater increase in both pulse and blood pressure, an increase of which will be temporary because of glucagon's short half-life. The increase in blood pressure and pulse rate may require therapy in patients with coronary artery disease.

4.6 Fertility, pregnancy and lactation

Pregnancy

Glucagon does not cross the human placenta barrier. The use of glucagon has been reported in pregnant women with diabetes and no harmful effects are known with respect to the course of pregnancy and the health of the unborn and the neonate. Ogluo can be used during pregnancy.

Breast-feeding

Glucagon is cleared from the bloodstream very fast (mainly by the liver) ($t_{1/2}$ = 3–6 minutes); thus the amount excreted in the milk of breast-feeding mothers following treatment of severe hypoglycaemic reactions is expected to be extremely small. As glucagon is degraded in the digestive tract and cannot be absorbed in its intact form, it will not exert any metabolic effect in the child. Ogluo can be used during breast-feeding.

Fertility

Animal reproduction studies have not been conducted with Ogluo. Studies in rats have shown that glucagon does not cause impaired fertility.

4.7 Effects on ability to drive and use machines

Ogluo has negligible influence on the ability to drive and use machines.

After a severe hypoglycaemic event, the patient's ability to concentrate and react may be impaired; therefore the patient should not drive or operate machinery after a severe hypoglycaemic event until the patient has stabilised.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions are nausea (30%) and vomiting (16%).

Tabulated list of adverse reactions

Frequencies of adverse reactions considered related to treatment with Ogluo during clinical trials are presented below. The adverse drug reactions are classified according to the System Organ Class. Frequency groups are defined by the following convention: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), and not known (cannot be estimated from available data). Within each frequency group, adverse reactions are presented in order of decreasing seriousness.

Table 1. Frequency of adverse reactions of glucagon injection

System organ class	Subject incidence	Adverse drug reaction
Nervous system disorders	Common	Headache
Cardiac disorders	Common	Tachycardia

System organ class	Subject incidence	Adverse drug reaction
Gastrointestinal disorders	Very common Very common Common Uncommon	Vomiting Nausea Diarrhoea Abdominal pain
General disorders and administration site conditions	Common Common Uncommon Uncommon	Injection site pain Injection site oedema Injection site bruising Injection site erythema

Description of selected adverse reactions

The most frequently reported adverse reactions are nausea (43%), vomiting (13%), and headache (5%). Adverse reactions are mild to moderate in severity and resolved on their own. No serious adverse reactions have been related to glucagon.

Hypersensitivity reactions, including anaphylactic reactions, have been reported as ‘very rare’ (<1/10,000 patients) with injectable glucagon. These are known medicinal product class effects of glucagon.

Paediatric population

The most frequently reported adverse reactions are nausea (48%), vomiting (19%), hyperglycaemia (7%), and headache (7%). Hypoglycaemia (42%) was observed in clinical trials but was not considered related to glucagon. The most frequently reported adverse reactions observed by age group are presented below.

Table 2. Frequency of most common adverse reactions among paediatric populations

	Ages 2 to under 6 years of age (0.5 mg dose) N = 7	Ages 6 to under 12 years of age (0.5 mg dose) N = 13	Ages 12 to under 18 (0.5 mg dose) N = 11	Ages 12 to under 18 (1 mg dose) N = 11
Nausea	43%	54%	36%	36%
Vomiting	14%	23%	0%	18%
Hyperglycaemia	14%	8%	0%	0%
Headache	0%	15%	0%	0%

Other special populations

Efficacy and safety data for Ogluo are very limited in patients aged 65 years and absent in patients aged 75 and above, in or pregnant patients, or patients with hepatic or renal impairment. Based upon data from clinical trials and post-marketing experience, the frequency, type, and severity of adverse reactions observed in elderly patients and in patients with renal or hepatic impairment are expected to be the same as in the general population.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in [Appendix V](#).

4.9 Overdose

If overdose occurs, the patient may experience nausea, vomiting, inhibition of gastro-intestinal tract motility, increase in blood pressure and pulse rate. In case of suspected overdosing, serum potassium may decrease and should be monitored and corrected if needed. If the patient develops a dramatic increase in blood pressure, use of non-selective α -adrenergic blockade has been shown to be effective in lowering blood pressure for the short time that control would be needed (see section 4.4).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Pancreatic hormones, glycogenolytic hormones: H04AA01.

Mechanism of action

Glucagon is a hyperglycaemic agent that mobilises hepatic glycogen, which is released into the blood as glucose. Hepatic stores of glycogen are necessary for glucagon to produce an anti-hypoglycaemic effect.

Pharmacodynamic effects

After administration of 1 mg Ogluo in adult patients with diabetes, the mean maximum plasma glucose increase from baseline was 176 mg/dL. After administration, plasma glucose begins to rise as early as 5 minutes. From the time of injection, the mean time to plasma glucose >70 mg/dL or ≥ 20 mg/dL increase was 14.8 (± 5.3) minutes.

Clinical efficacy and safety

Ogluo was evaluated in 132 adult patients aged 18 to 74 years with type 1 diabetes in a multicentre randomised, active-controlled, single-blind, 2-way crossover study. The study involved 2 clinic visits 7 to 28 days apart, with random assignment to receive glucagon 1 mg solution for injection during one session and reconstituted glucagon 1 mg powder and solvent for solution for injection during the other. A total of 127 subjects received an injection of Ogluo and 123 subjects received a glucagon powder and solvent for solution for injection.

The efficacy of glucagon 1 mg solution for injection was compared to reconstituted glucagon 1 mg powder and solvent for solution for injection in subjects who were in a state of insulin-induced hypoglycaemia with target plasma glucose less than 3.0 mmol/L (<54 mg/dL). Treatment 'success' was defined as plasma glucose increase from time of glucagon administration to absolute value greater than 3.89 mmol/L (>70 mg/dL) or relative increase of 1.11 mmol/L (≥ 20 mg/dL) or greater, within 30 minutes after glucagon administration. The proportion of patients who achieved treatment 'success' was 99.2% in the glucagon 1 mg solution for injection group and 100% in the reconstituted glucagon 1 mg powder and solvent for solution for injection group, and the comparison between groups met the prespecified non-inferiority margin.

From the time of administration, which does not include the preparation time for each medicinal product prior to administration the mean time to treatment ‘success’ was 14.8 (± 5.3) minutes in the glucagon 1 mg solution for injection group and 10.4 (± 1.8) minutes in the reconstituted glucagon 1 mg powder and solvent for solution for injection group.

From the time of decision to dose, which includes the preparation time for each medicinal product prior to administration, the mean time to treatment ‘success’ was 15.6 (± 5.2) minutes in the glucagon 1 mg solution for injection group and 12.2 (± 2.0) minutes in the reconstituted glucagon 1 mg powder and solvent for solution for injection.

Paediatric population

Ogluo was evaluated in 31 pediatric patients ages 2 to 18 years (7 patients in the 2-<6, 13 patients in the 6-<12 and 11 patients in the 12-<18 years old group) with T1DM in an open-label, sequential, uncontrolled clinical study. Efficacy was assessed based on increases from Baseline in mean plasma glucose 30 minutes post-dosing. Statistically significant changes from Baseline of 81.4 mg/dL [SD=18.3], 84.2 mg/dL [SD=25.3], and 54.0 mg/dL [SD=27.3] were observed in the 2-< 6 years, 6-<12 years, and 12-< 18 years [1 mg dose] age groups, respectively). Across all 31 subjects the mean time to plasma glucose increase ≥ 25 mg/dL from baseline was 18.9 minutes.

In paediatric patients with type 1 diabetes (2 to <18 years), the mean maximum glucose increase from baseline was 134 mg/dL (2 to <6 years), 145 mg/dL (6 to <12 years), and 123 mg/dL (12 to <18 years).

5.2 Pharmacokinetic properties

Absorption

Subcutaneous injection of 1 mg Ogluo in adult type 1 diabetes mellitus subjects resulted in a mean glucagon C_{\max} of 2481.3 pg/mL, t_{\max} of 50 minutes and $AUC_{0-240\min}$ of 3454.6 pg*hr/mL.

Distribution

The apparent volume of distribution was in the range of 137-2425 Liters.

Metabolism

Glucagon is extensively degraded in liver, kidney, and plasma.

Elimination

The mean half-life of Ogluo was determined to be 31.9 ± 9.13 minutes.

Paediatric population

Subcutaneous injection of 0.5 mg Ogluo in subjects with type 1 diabetes mellitus ages 2 to under 6 years resulted in a mean glucagon C_{\max} of 2 300 pg/mL, t_{\max} of 41 minutes, and $AUC_{0-180\min}$ of 138 900 pg/mL*min. Subcutaneous injection of 0.5 mg Ogluo in subjects with type 1 diabetes mellitus ages 6 to under 12 years resulted in a mean C_{\max} of 1 600 pg/mL, median t_{\max} of 34 minutes and $AUC_{0-180\min}$ of 104 700 pg/mL*min. Subcutaneous injection of 1 mg Ogluo in subjects with type 1 diabetes mellitus ages 12 to less than 18 years resulted in a mean C_{\max} of 1 900 pg/mL, t_{\max} of 51 minutes $AUC_{0-180\min}$ of 134 300 pg/mL*min.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trehalose Dihydrate
Dimethyl sulfoxide (DMSO)
Sulfuric Acid
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Ogluo 0.5 mg solution for injection in pre-filled pen.
Ogluo 0.5 mg solution for injection in pre-filled syringe.

2 years.

Ogluo 1 mg solution for injection in pre-filled pen.
Ogluo 1 mg solution for injection in pre-filled syringe.

30 months

6.4 Special precautions for storage

Do not store above 25°C.

Do not refrigerate or freeze. Do not store below 15°C.

Store in original sealed foil pouch until time of use in order to protect from light and moisture.

6.5 Nature and contents of container

Ogluo 0.5 mg solution for injection in pre-filled pen

A pre-filled, single-dose pen containing a 1 mL cyclic olefin polymer syringe with ETFE coated chlorobutyl rubber piston, 27-gauge staked stainless steel needle, bromo butyl rubber flexible needle shield, and a red cap.

Each pre-filled pen contain 0.1 mL of solution for injection and is individually packaged in a predominantly red-coloured foil pouch, in a red on white carton displaying a pre-filled pen image.

Pack sizes of one and two single-dose pre-filled pens.

Ogluo 1 mg solution for injection in pre-filled pen

A pre-filled, single-dose pen containing a 1 mL cyclic olefin polymer syringe with ETFE coated chlorobutyl rubber piston, 27-gauge staked stainless steel needle, bromo butyl rubber flexible needle shield, and a red cap.

Each pre-filled pen contains 0.2 mL of solution for injection and is individually packaged in a predominantly blue-coloured foil pouch, in a blue on white carton displaying a pre-filled pen image.

Pack sizes of one and two single-dose pre-filled pens.

Ogluo 0.5 mg solution for injection in pre-filled syringe

A pre-filled 1 mL cyclic olefin polymer syringe with ETFE coated chlorobutyl rubber piston, 27-gauge staked stainless steel needle, and bromo butyl rubber rigid needle shield. Each syringe contains 0.1 mL of solution for injection and is individually packaged in a predominantly red-coloured foil pouch, in a red on white carton displaying a pre-filled syringe image.

Pack sizes of one and two single-dose pre-filled syringes.

Ogluo 1 mg solution for injection in pre-filled syringe

A pre-filled 1 mL cyclic olefin polymer syringe with ETFE coated chlorobutyl rubber piston, 27-gauge staked stainless steel needle, and bromo butyl rubber rigid needle shield. Each syringe contains 0.2 mL of solution for injection and is individually packaged in a predominantly blue-coloured foil pouch, in a blue on white carton displaying a pre-filled syringe image.

Pack sizes of one and two single-dose pre-filled syringes.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

This is a ready to use medicinal product and for single-use only.

The single-dose device contains only one dose.

The instructions for using the medicinal product in the package leaflet must be followed carefully.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Tetris Pharma B.V
Bargelaan 200
Element Offices
2333 CW Leiden
Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/20/1523/001
EU/1/20/1523/002
EU/1/20/1523/003
EU/1/20/1523/004
EU/1/20/1523/005
EU/1/20/1523/006
EU/1/20/1523/007
EU/1/20/1523/008

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 February 2021

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>

ANNEX II

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**
- D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

AcertiPharma B.V.,
Boschstraat 51,
Breda, 4811 GC,
Netherlands

Manufacturing Packaging Farmaca (MPF) B.V.
Neptunus 12
Heerenveen, 8448CN
Netherlands

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European Medicines Agency web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

- **Additional risk minimisation measures**

Prior to launch of Ogluo (glucagon), for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus, in each EU Member State, the Marketing Authorisation Holder (MAH) must agree on the content and format of the educational materials, including communication media, distribution modalities, and any other aspects of the programme, with National Competent Authority.

The educational materials are aimed at providing guidance on how to minimise the important potential risk in the RMP of inappropriate use of the device leading to loss of drug benefit.

The MAH shall ensure that in each Member State where Ogluo is marketed, all healthcare professionals and patients/caregivers who are expected to prescribe, supply, or use the medicinal product have access to the following:

- Administration leaflet;
- Instructional video.

The **administration leaflet** should contain the following key elements:

- Patients should receive the administration leaflet from their healthcare professionals upon initial Ogluo prescription and after training.
- It is important not to test the single-dose device in advance, not to remove the single-dose device from the foil pouch in advance and to ensure that the patient understands that each Ogluo single-dose device can only be used once.
- The PL should be referenced for more detailed information regarding administration and handling of Ogluo.
- Patients can use the leaflet to teach those around them how to correctly handle and administer Ogluo.
- If the patient does not respond within 15 minutes, an additional dose of Ogluo from a new device may be administered while waiting for emergency assistance.
- The leaflet should contain a URL and QR code to a website where patients can access the instructional video.

The **instructional video** should contain the following key elements:

- To reinforce the correct Ogluo handling and administration, step-by-step instructions on the appropriate use of Ogluo should be provided.
- If the patient does not respond within 15 minutes, an additional dose of Ogluo from a new device may be administered while waiting for emergency assistance.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**OUTER CARTON – PRE-FILLED PEN (0.5 MG)****1. NAME OF THE MEDICINAL PRODUCT**

Ogluo 0.5 mg solution for injection in pre-filled pen
glucagon

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 0.5 mg glucagon in 0.1 mL

3. LIST OF EXCIPIENTS

Also contains trehalose dihydrate, dimethyl sulfoxide (DMSO), sulfuric acid and water for injections.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

1 single-dose pre-filled pen
2 single-dose pre-filled pens

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use
subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY**8. EXPIRY DATE**

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not refrigerate or freeze. Do not store below 15°C.

Store in original sealed foil pouch until time of use in order to protect from light and moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE
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Any unused medicinal product or waste material should be disposed of in accordance with local requirements

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Tetris Pharma B.V
Bargelaan 200
Element Offices
2333 CW Leiden
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)
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EU/1/20/1523/001 - Ogluo 0.5 mg solution for injection in pre-filled pen – 1 single-dose pen
EU/1/20/1523/002 - Ogluo 0.5 mg solution for injection in pre-filled pen – 2 single-dose pens

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY
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15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Ogluo 0.5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA
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PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

POUCH FOIL – PRE-FILLED PEN (0.5 MG)

1. NAME OF THE MEDICINAL PRODUCT

Ogluo 0.5 mg solution for injection in pre-filled pen
glucagon

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 0.5 mg glucagon in 0.1 mL

3. LIST OF EXCIPIENTS

Also contains trehalose dihydrate, dimethyl sulfoxide (DMSO), sulfuric acid and water for injections.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

1 single-dose pre-filled pen

5. METHOD AND ROUTE(S) OF ADMINISTRATION

1. Prepare

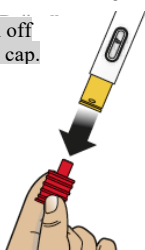
- Tear open pouch at dotted line. Remove pen.

Tear open pouch
at dotted line.
Remove pen.

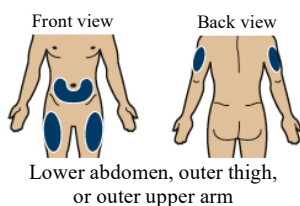


- Pull off red cap.
- Choose injection site and expose bare skin.

Pull off
red cap.



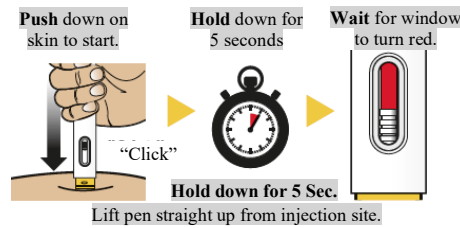
Choose injection site and expose bare skin.



2. Inject

- **Push** down on skin to start.

- **Hold** down for 5 seconds.
- **Wait** for window to turn red.



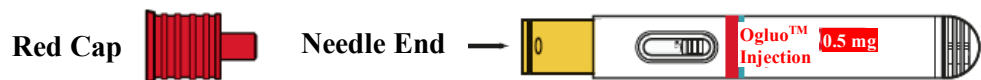
- Lift pen straight up from injection site.

3. Assist

- Turn patient on side.
Call emergency medical help.
Turn patient on side.
Call emergency medical help.



- After injection the yellow needle guard will lock over the needle.



Read the package leaflet before use

subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not refrigerate or freeze. Do not store below 15°C.

Store in original sealed foil pouch until time of use in order to protect from light and moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE
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Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Tetris Pharma B.V
Bargelaan 200
Element Offices
2333 CW Leiden
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)
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EU/1/20/1523/001 - Ogluo 0.5 mg solution for injection in pre-filled pen – 1 single-dose pen
EU/1/20/1523/002 - Ogluo 0.5 mg solution for injection in pre-filled pen – 2 single-dose pens

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY
--

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA
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MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – PRE-FILLED PEN (0.5 MG)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Ogluo 0.5 mg injection
glucagon

subcutaneous use

2. METHOD OF ADMINISTRATION

Single-dose

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 mg

6. OTHER

Needle end

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**OUTER CARTON – PRE-FILLED PEN (1 MG)****1. NAME OF THE MEDICINAL PRODUCT**

Ogluo 1 mg solution for injection in pre-filled pen
glucagon

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 1 mg glucagon in 0.2 mL

3. LIST OF EXCIPIENTS

Also contains trehalose dihydrate, dimethyl sulfoxide (DMSO), sulfuric acid and water for injections.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

1 single-dose pre-filled pen
2 single-dose pre-filled pens

5. METHOD AND ROUTE(S) OF ADMINISTRATION

subcutaneous sse

Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY**8. EXPIRY DATE**

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not refrigerate or freeze. Do not store below 15°C.

Store in original sealed foil pouch until time of use in order to protect from light and moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE
--

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Tetris Pharma B.V
Bargelaan 200
Element Offices
2333 CW Leiden
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)
--

EU/1/20/1523/005 - Ogluo 1 mg solution for injection in pre-filled pen – 1 single-dose pen
EU/1/20/1523/006 - Ogluo 1 mg solution for injection in pre-filled pen – 2 single-dose pens

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY
--

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Ogluo 1 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA
--

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

POUCH FOIL – PRE-FILLED PEN (1 MG)

1. NAME OF THE MEDICINAL PRODUCT

Ogluo 1 mg solution for injection in pre-filled pen
glucagon

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 1 mg glucagon in 0.2 mL

3. LIST OF EXCIPIENTS

Also contains trehalose dihydrate, dimethyl sulfoxide (DMSO), sulfuric acid and water for injections.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

1 single-dose pre-filled pen

5. METHOD AND ROUTE(S) OF ADMINISTRATION

1. Prepare

- Tear open pouch at dotted line. Remove pen.

Tear Open Pouch
at dotted line.
Remove pen.

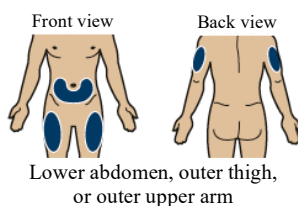


- Pull off red cap.
- Choose injection site and expose bare skin.

Pull off
red cap.



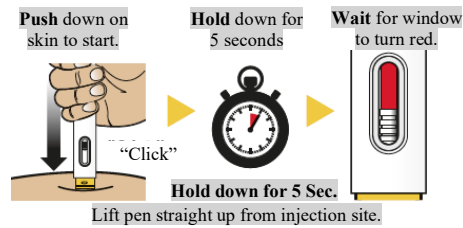
Choose injection site and expose bare skin.



2. Inject

- **Push** down on skin to start.

- **Hold** down for 5 seconds.
- **Wait** for window to turn red.



- Lift pen straight up from injection site.

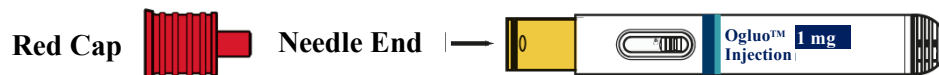
3. Assist

- Turn patient on side.
- Call emergency medical help.

Turn patient on side.
Call emergency
medical help.



- After injection the yellow needle guard will lock over the needle.



Read the package leaflet before use

subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not refrigerate or freeze. Do not store below 15°C.

Store in original sealed foil pouch until time of use in order to protect from light and moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE
--

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Tetris Pharma B.V
Bargelaan 200
Element Offices
2333 CW Leiden
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)
--

EU/1/20/1523/005 - Ogluo 1 mg solution for injection in pre-filled pen – 1 single-dose pen
EU/1/20/1523/006 - Ogluo 1 mg solution for injection in pre-filled pen – 2 single-dose pens

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY
--

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA
--

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – PRE-FILLED PEN (1 MG)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Ogluo 1 mg injection
glucagon

subcutaneous use

2. METHOD OF ADMINISTRATION

single-dose

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 mg

6. OTHER

Needle end

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**OUTER CARTON – PRE-FILLED SYRINGE (0.5 MG)****1. NAME OF THE MEDICINAL PRODUCT**

Ogluo 0.5 mg solution for injection in pre-filled syringe
glucagon

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled syringe contains 0.5 mg glucagon in 0.1 mL

3. LIST OF EXCIPIENTS

Also contains trehalose dihydrate, dimethyl sulfoxide (DMSO), and sulfuric acid, water for injection.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

1 single-dose pre-filled syringe
2 single-dose pre-filled syringes

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use
subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY**8. EXPIRY DATE**

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not refrigerate or freeze. Do not store below 15°C.

Store in original sealed foil pouch until time of use in order to protect from light and moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Tetris Pharma B.V
Bargelaan 200
Element Offices
2333 CW Leiden
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/20/1523/003 - Ogluo 0.5 mg solution for injection in pre-filled syringe – 1 single-dose syringe
EU/1/20/1523/004 - Ogluo 0.5 mg solution for injection in pre-filled syringe – 2 single-dose syringes

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Ogluo 0.5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING
POUCH FOIL – PRE-FILLED SYRINGE (0.5 MG)**

1. NAME OF THE MEDICINAL PRODUCT

Ogluo 0.5 mg solution for injection in pre-filled syringe
glucagon

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled syringe contains 0.5 mg glucagon in 0.1 mL

3. LIST OF EXCIPIENTS

Also contains trehalose dihydrate, dimethyl sulfoxide (DMSO), and sulfuric acid, water for injection.
See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

1 single-dose pre-filled syringe

5. METHOD AND ROUTE(S) OF ADMINISTRATION

1. Prepare

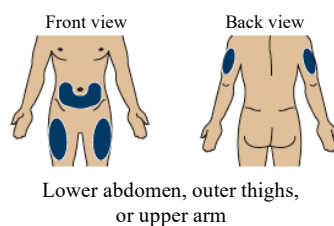
- Tear open pouch at dotted line. Remove syringe.

Tear open pouch at
dotted line. Remove
syringe.



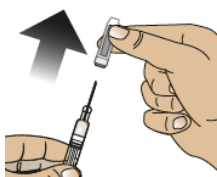
- Choose injection site and expose bare skin.

Choose injection site and expose bare skin.



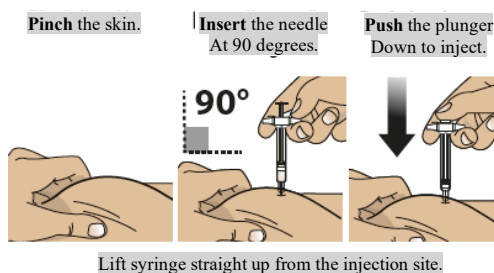
- Pull off needle cap.
- Do **not** remove air bubbles.

Pull off needle cap.
Do **NOT** remove air bubbles.



2. Inject

- **Pinch** the skin.
- **Insert** the needle at 90 degrees.
- **Push** the plunger down to inject.



- Lift the syringe straight up from the injection site.

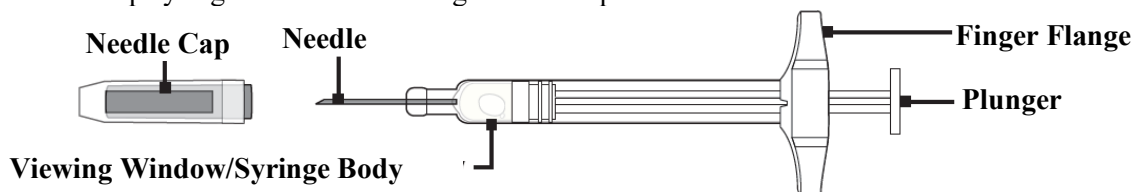
3. Assist

- Turn patient on side.
- Call emergency medical help

Turn patient on side.
Call emergency
medical help.



Do not recap syringe. Discard according to local requirements.



subcutaneous use

Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not refrigerate or freeze. Do not store below 15°C.

Store in original sealed foil pouch until time of use in order to protect from light and moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Tetris Pharma B.V
Bargelaan 200
Element Offices
2333 CW Leiden
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/20/1523/003 - Ogluo 0.5 mg solution for injection in pre-filled syringe – 1 single-dose syringe
EU/1/20/1523/004 - Ogluo 0.5 mg solution for injection in pre-filled syringe – 2 single-dose syringes

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY**15. INSTRUCTIONS ON USE****16. INFORMATION IN BRAILLE**

17. UNIQUE IDENTIFIER – 2D BARCODE
--

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS LABEL – PRE-FILLED SYRINGE (0.5 MG)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION
--

Ogluo 0.5 mg injection
glucagon

subcutaneous use

2. METHOD OF ADMINISTRATION

Single-dose

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT
--

0.5 mg

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**OUTER CARTON – PRE-FILLED SYRINGE (1 MG)****1. NAME OF THE MEDICINAL PRODUCT**

Ogluo 1 mg solution for injection in pre-filled syringe
glucagon

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled syringe contains 1 mg glucagon in 0.2 mL

3. LIST OF EXCIPIENTS

Also contains trehalose dihydrate, dimethyl sulfoxide (DMSO), and sulfuric acid, water for injection.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

1 single-dose pre-filled syringe
2 single-dose pre-filled syringes

5. METHOD AND ROUTE(S) OF ADMINISTRATION

subcutaneous use

Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY**8. EXPIRY DATE**

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not refrigerate or freeze. Do not store below 15°C.

Store in original sealed foil pouch until time of use in order to protect from light and moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE
--

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Tetris Pharma B.V
Bargelaan 200
Element Offices
2333 CW Leiden
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)
--

EU/1/20/1523/007 - Ogluo 1 mg solution for injection in pre-filled syringe – 1 single-dose syringe
EU/1/20/1523/008 - Ogluo 1 mg solution for injection in pre-filled syringe – 2 single-dose syringes

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY
--

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Ogluo 1 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA
--

PC
SN
NN

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING
POUCH FOIL – PRE-FILLED SYRINGE (1 MG)**

1. NAME OF THE MEDICINAL PRODUCT

Ogluo 1 mg solution for injection in pre-filled syringe
glucagon

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled syringe contains 1 mg glucagon in 0.2 mL

3. LIST OF EXCIPIENTS

Also contains trehalose dihydrate, dimethyl sulfoxide (DMSO), and sulfuric acid, water for injection.
See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

1 single-dose pre-filled syringe

5. METHOD AND ROUTE(S) OF ADMINISTRATION

subcutaneous use

Read the package leaflet before use

1. Prepare

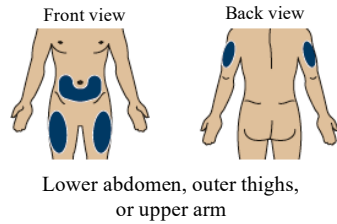
- Tear open pouch at dotted line. Remove syringe.

Tear open pouch at
dotted line. Remove
syringe.



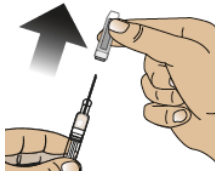
- Choose injection site and expose bare skin.

Choose injection site and expose bare skin.



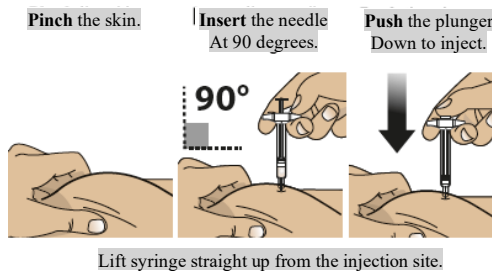
- Pull off needle cap.
- Do **not** remove air bubbles.

Pull off needle cap.
Do **NOT** remove air bubbles.



2. Inject

- **Pinch** the skin.
- **Insert** the needle at 90 degrees.
- **Push** the plunger down to inject.



- Lift the syringe straight up from the injection site.

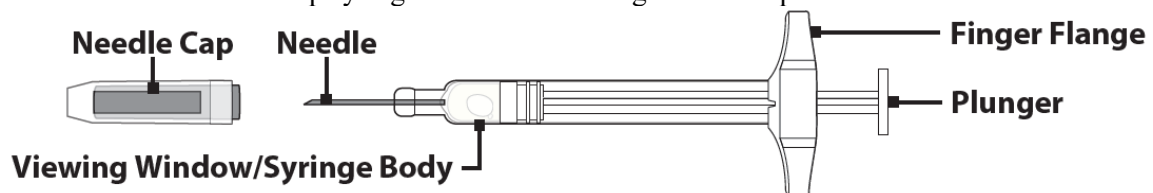
3. Assist

- Turn patient on side.
- Call emergency medical help

Turn patient on side.
Call emergency medical
help.



- Do not recap syringe. Discard according to local requirements.



subcutaneous use

Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not refrigerate or freeze. Do not store below 15°C.

Store in original sealed foil pouch until time of use in order to protect from light and moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Tetris Pharma B.V
Bargelaan 200
Element Offices
2333 CW Leiden
Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/20/1523/007 - Ogluo 1 mg solution for injection in pre-filled syringe – 1 single-dose syringe
EU/1/20/1523/008 - Ogluo 1 mg solution for injection in pre-filled syringe – 2 single-dose syringes

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA
--

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS LABEL – PRE-FILLED SYRINGE (1 MG)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION
--

Ogluo 1 mg injection
glucagon

subcutaneous use

2. METHOD OF ADMINISTRATION

single-dose

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT
--

1 mg

6. OTHER

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Ogluo 0.5 mg solution for injection in pre-filled pen Ogluo 1 mg solution for injection in pre-filled pen glucagon

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ogluo is and what it is used for
2. What you need to know before you use Ogluo
3. How to use Ogluo
4. Possible side effects
5. How to store Ogluo
6. Contents of the pack and other information

1. What Ogluo is and what it is used for

Ogluo contains the active substance glucagon, which belongs to a group of medicines called glycogenolytic hormones.

It is used to treat severe hypoglycaemia (very low blood sugar) in people with diabetes. It is for use in adults, adolescents, and children aged 2 years or older.

Ogluo is a ready-to-use, pre-filled pen that contains a single dose of the active substance, glucagon. It is a subcutaneous injection, meaning that the medicine is administered under the skin using a needle.

Glucagon is a natural hormone produced by the pancreas, which has the opposite effect of insulin in the human body. It helps the liver to convert stored sugar in the liver called 'glycogen' into glucose (sugar). Glucose is then released into the blood stream, which makes the blood sugar level rise, reducing the effects of hypoglycaemia.

Information on hypoglycaemia

Early symptoms of hypoglycaemia (low blood sugar) include:

- | | |
|----------------------|--|
| • sweating | • slurred speech |
| • drowsiness | • depressed mood |
| • dizziness | • tingling in the hands, feet, lips, or tongue |
| • sleep disturbances | • irritability |
| • palpitation | • light-headedness |
| • anxiety | • abnormal behaviour |
| • tremor | • inability to concentrate |
| • blurred vision | • unsteady movement |
| • hunger | |

- headache
- personality changes

If not treated, the patient may progress to severe hypoglycemia which can include:

- confusion
- seizures
- unconsciousness
- death

2. What you need to know before you use Ogluo

Important information

- Make sure that you, your family members, people you work with, and close friends know about Ogluo. Tell them that if you show any signs of severe hypoglycaemia, including confusion, seizures, or unconsciousness (pass out) they should use Ogluo straight away. You should always carry Ogluo with you.
- It is important that you or those around you know how to use Ogluo before you need it. Show your family members and others where you keep Ogluo and how to use it. They must act quickly if you become unconscious because if this happens for a period of time, it may be harmful. You, or the person administering Ogluo to you, should follow the instructions in Section 3 of this leaflet: 'How to use Ogluo'.
- It is important that you store Ogluo correctly to make sure that it can be used straight away if you need it. See Section 5 for more information on how to store this medicine properly.

Do not use Ogluo if:

- You are allergic to glucagon or any of the other ingredients in this medicine (listed in Section 6).
- You have a tumour in your adrenal gland (pheochromocytoma).

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before using Ogluo.

Ogluo may not work properly if:

- You have been fasting or have had low blood sugar levels for a long time
- You have low levels of adrenaline
- You have low blood sugar caused by drinking too much alcohol
- You have a tumour that releases glucagon or insulin

If any of these apply to you, talk to your doctor or pharmacist.

Please take into account that approximately 15% of patients achieved glucose recovery after 20 minutes or more in the pivotal trial.

After using Ogluo, eat as soon as possible to prevent the recurrence of low blood sugar. Take a fast-acting source of sugar, such as fruit juice or a sugar-containing carbonated drink.

Children

Ogluo is not recommended for children under 2 years of age because it has not been studied in this age group.

Other medicines and Ogluo

Tell your doctor if you are taking, have recently taken, or might take any other medicines.

The following medicines can affect the way that Ogluo works:

- Insulin – used to treat diabetes. Insulin has the opposite effect of glucagon on blood sugar.
- Indomethacin – used to treat joint pain and stiffness. Indomethacin reduces the effect of glucagon.

Ogluo can affect the way that the following medicines work:

- Warfarin – used to prevent blood clots. Ogluo may increase the blood-thinning effect of warfarin.
- Beta-blockers – used to treat high blood pressure and irregular heart beat. Ogluo may increase your blood pressure and pulse but this will only last a short time.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Ogluo.

Pregnancy, breast-feeding and fertility

If you experience very low blood sugar when you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, you can use Ogluo.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant.

Driving and using machines

After a severe hypoglycaemic event your ability to concentrate and react may be reduced, you should wait until the effects of very low blood sugar have worn off, and you feel better, before driving or using any tools or machines.

3. How to use Ogluo

Always use (or give) this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Ogluo is given as an injection under the skin (subcutaneous injection). It is supplied in a pen. The injector pen contains a measured amount of medicine, so if you follow these instructions, the whole dose is administered.

Prepare

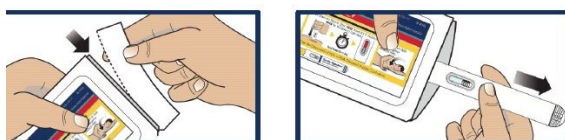
Check the expiry date printed on the pouch.

Important:

Do not use this medicine if the expiry date has passed. If this medicine is expired, throw it away in accordance with local requirements and use a new one.

Tear open the pouch at the dotted line and remove the pen (see Figure 1).

Figure 1



Inspect the solution

Look at the liquid medicine through the viewing window. It must be clear and colourless, or a pale yellow (see Figure 2).

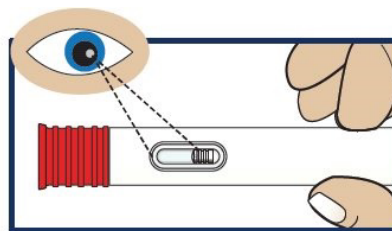
Important:

Do not use this medicine or inject if the liquid is discoloured, contains lumps, flakes, or particles. Do not inject if solution is not visible in the viewing window.

After injection, call for emergency medical help right away.

Each pen contains a single dose of glucagon and cannot be reused.

Figure 2

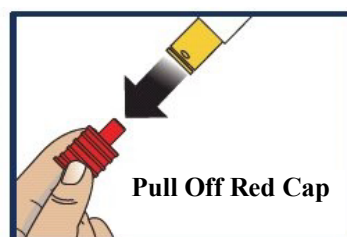


Pull the red needle cap straight off of the device (see Figure 3).

Important:

Do not put your thumb, fingers, or hand on or near the needle guard or needle opening to help prevent accidental needle sticks.

Figure 3



Inject

Choose injection site and expose bare skin.

Choose the lower abdomen, outer thigh, or outer upper arm for your injection site (see Figure 4).

Remove any clothing covering the injection site (see Figure 5). The injection must be performed straight into the skin.

Important:

Do not inject through clothing.

Figure 4

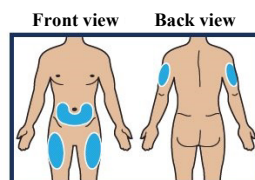


Figure 5



Push and hold this medicine straight down against the injection site. Listen for a “click”.

Continue to hold the device down and count slowly to 5 (see Figure 6).

When the injection is complete, the viewing window will be red (see Figure 7).

Important:

Do not lift up this medicine until the injection is complete.

Figure 6

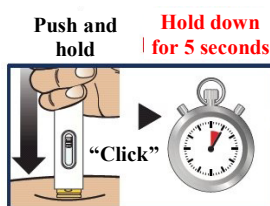
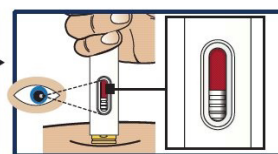


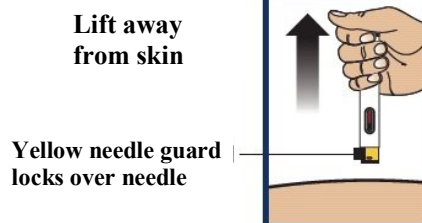
Figure 7



Lift the pen straight up from the injection site (see Figure 8).

The yellow needle guard will lock over the needle.

Figure 8



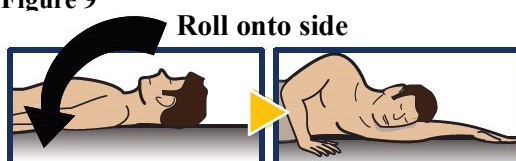
Assist

Turn patient onto side.

When an unconscious person wakes up, he or she may be sick (vomit). If the patient is unconscious, turn them on their side to prevent choking (see Figure 9).

Call for emergency medical help right after Ogluo has been injected. When the patient has responded to the treatment, give him/her a fast-acting source of sugar, such as fruit juice or a sugar-containing carbonated drink to prevent the recurrence of low blood sugar. If the patient does not respond within 15 minutes, an additional dose of Ogluo from a new device may be administered while waiting for emergency assistance.

Figure 9



How much to use

This medicine contains either 0.5 mg or 1 mg of the active substance in a fixed dose of medicine. You will be prescribed the correct strength (dose) of medicine for your own personal use.

The recommended dose for adults, adolescents, and children is shown in the table below. For children under 6 years, the recommended dose will depend on how much they weigh.

Age	Weight	Recommended dose of Ogluo
Children, ages 2 years to under 6 years	Less than 25 kg	0.5 mg
Children, ages 2 years to under 6 years	More than or equal to 25 kg	1 mg
Adults and adolescents, 6 years and over	Not Applicable	1 mg

After using this medicine, eat as soon as possible to prevent the recurrence of low blood sugar. Take a fast-acting source of sugar, such as fruit juice or a sugar-containing carbonated drink.

If you use more Ogluo than you should

Too much medicine may make you feel sick (nausea) or cause you to be sick (vomit). Specific treatment is not usually necessary.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor or a healthcare professional immediately if you notice any of the following serious side effects:

Very rare (may affect up to 1 in 10,000 people)

- allergic reaction – signs may include wheezing, sweating, rapid heartbeat, rash, swollen face (i.e, swelling of the face, lips, tongue, and throat which may cause difficulty in swallowing or breathing), or collapse. Allergic reaction has not been reported with Ogluo, but has been seen in other injectable glucagon medicines. You should seek help urgently if you experience symptoms of an allergic reaction.

Other side effects may include:

Very common (may affect more than 1 in 10 people)

- feeling sick (nausea)
- being sick (vomiting)

Common (may affect up to 1 in 10 people)

- headache
- fast heartbeat (tachycardia)
- discomfort or a reaction at the site of injection
- injection site oedema (swelling)
- diarrhoea

Uncommon (may affect up to 1 in 100 people)

- abdominal pain
- injection site bruising
- injection site erythema (redness)

Additional side effects in children

Common (may affect up to 1 in 10 people)

- hyperglycaemia
- abdominal pain

- urticaria (swelling/redness)
- head injury
- dizziness

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ogluo

Do not use this medicine after the expiry date which is stated on the pen, pouch, and carton. The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children.

This medicine should not be stored above 25°C.

Do not refrigerate or freeze. Do not store below 15°C.

Store in the foil pouch before use to protect from light and moisture.

Do not use this medicine if you notice the solution is discoloured or contains particulate matter.

Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ogluo contains

- The active substance in Ogluo is glucagon.
 - *Ogluo 0.5 mg solution for injection in pre-filled pen*
Each pre-filled pen contains 0.5 mg glucagon in 0.1 mL.
 - *Ogluo 1 mg solution for injection in pre-filled pen*
Each pre-filled pen contains 1 mg glucagon in 0.2 mL.
- The other ingredients are trehalose dihydrate, dimethyl sulfoxide (DMSO), sulfuric acid, and water for injections.

What Ogluo looks like and the contents of the pack

Ogluo is a clear, colourless to pale yellow solution. It is produced in a ready-to-use, pre-filled, single-dose pen, containing either 0.5 mg or 1 mg of glucagon. Each medicine is individually packaged in a foil pouch. A full list of the available Ogluo medicines is provided below.

- Ogluo 0.5 mg solution for injection in pre-filled pen, pack of 1 or 2 single-dose pre-filled pens.
- Ogluo 1 mg solution for injection in pre-filled pen, pack of 1 or 2 single-dose pre-filled pens.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Tetris Pharma B.V
Bargelaan 200
Element Offices
2333 CW Leiden
Netherlands

Manufacturer:

AcertiPharma B.V.,
Boschstraat 51,
Breda, 4811 GC,
Netherlands

Manufacturing Packaging Farmaca (MPF) B.V.
Neptunus 12
Heerenveen, 8448CN
Netherlands

This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

Package leaflet: Information for the user

Ogluo 0.5 mg solution for injection in pre-filled syringe Ogluo 1 mg solution for injection in pre-filled syringe glucagon

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ogluo is and what it is used for
2. What you need to know before you use Ogluo
3. How to use Ogluo
4. Possible side effects
5. How to store Ogluo
6. Contents of the pack and other information

1. What Ogluo is and what it is used for

Ogluo contains the active substance glucagon, which belongs to a group of medicines called glycogenolytic hormones.

It is used to treat severe hypoglycaemia (very low blood sugar) in people with diabetes. It is for use in adults, adolescents, and children aged 2 years or older.

Ogluo is a ready-to-use, pre-filled syringe that contains a single dose of the active substance, glucagon. It is a subcutaneous injection, meaning that the medicine is administered under the skin using a needle.

Glucagon is a natural hormone produced by the pancreas, which has the opposite effect of insulin in the human body. It helps the liver to convert stored sugar in the liver called 'glycogen' into glucose (sugar). Glucose is then released into the blood stream, which makes the blood sugar level rise, reducing the effects of hypoglycaemia.

Information on hypoglycaemia

Early symptoms of hypoglycaemia (low blood sugar) include:

- | | |
|----------------------|--|
| • sweating | • hunger |
| • drowsiness | • slurred speech |
| • dizziness | • depressed mood |
| • sleep disturbances | • tingling in the hands, feet, lips, or tongue |
| • palpitation | • irritability |
| • anxiety | • light-headedness |
| • tremor | • abnormal behaviour |
| • blurred vision | |

- inability to concentrate
- unsteady movement
- headache
- personality changes

If not treated, the patient may progress to severe hypoglycemia which can include:

- confusion
- seizures
- unconsciousness
- death

2. What you need to know before you use Ogluo

Important information

- Make sure that you, your family members, people you work with, and close friends know about Ogluo. Tell them that if you show any signs of severe hypoglycaemia, including confusion, seizures, or unconsciousness (pass out) they should use Ogluo straight away. You should always carry Ogluo with you.
- It is important that you or those around you know how to use Ogluo before you need it. Show your family members and others where you keep Ogluo and how to use it. They must act quickly if you become unconscious because if this happens for a period of time, it may be harmful. You, or the person administering Ogluo to you, should follow the instructions in Section 3 of this leaflet: 'How to use Ogluo'.
- It is important that you store Ogluo correctly to make sure that it can be used straight away if you need it. See Section 5 for more information on how to store this medicine properly.

Do not use Ogluo if:

- You are allergic to glucagon or any of the other ingredients in this medicine (listed in Section 6).
- You have a tumour in your adrenal gland (pheochromocytoma).

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before using Ogluo.

Ogluo may not work properly if:

- You have been fasting or have had low blood sugar levels for a long time
- You have low levels of adrenaline
- You have low blood sugar caused by drinking too much alcohol
- You have a tumour that releases glucagon or insulin

If any of these apply to you, talk to your doctor or pharmacist.

Please take into account that approximately 15% of patients achieved glucose recovery after 20 minutes or more in the pivotal trial.

After using Ogluo, eat as soon as possible to prevent the recurrence of low blood sugar. Take a fast-acting source of sugar, such as fruit juice or a sugar-containing carbonated drink.

Children

Ogluo is not recommended for children under 2 years of age because it has not been studied in this age group.

Other medicines and Ogluo

Tell your doctor if you are taking, have recently taken, or might take any other medicines.

The following medicines can affect the way that Ogluo works:

- Insulin – used to treat diabetes. Insulin has the opposite effect of glucagon on blood sugar.
- Indomethacin – used to treat joint pain and stiffness. Indomethacin reduces the effect of glucagon.

Ogluo can affect the way that the following medicines work:

- Warfarin – used to prevent blood clots. Ogluo may increase the blood-thinning effect of warfarin.
- Beta-blockers – used to treat high blood pressure and irregular heart beat. Ogluo may increase your blood pressure and pulse but this will only last a short time.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Ogluo.

Pregnancy, breast-feeding and fertility

If you experience very low blood sugar when you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, you can use Ogluo.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant.

Driving and using machines

After a severe hypoglycaemic event your ability to concentrate and react may be reduced, you should wait until the effects of very low blood sugar have worn off, and you feel better, before driving or using any tools or machines.

3. How to use Ogluo

Always use (or give) this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Ogluo is given as an injection under the skin (subcutaneous injection). It is supplied in a pre-filled syringe, meaning that it contains a measured amount of medicine. If you follow these instructions, the whole dose is administered.

Prepare

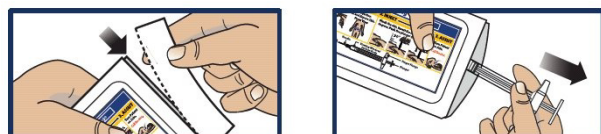
Check the expiry date printed on the pouch.

Important:

Do not use this medicine if the expiry date has passed. If this medicine is expired, throw it away in accordance with local requirements and use a new one.

Tear open the pouch at the dotted line and remove the pre-filled syringe (see Figure 1).

Figure 1



Inspect the solution

Look at the liquid medicine through the syringe. It must be clear and colourless, or a pale yellow (see Figure 2).

It is normal to see air bubbles in the medicine.

Important:

Do not try to remove air bubbles before injecting.

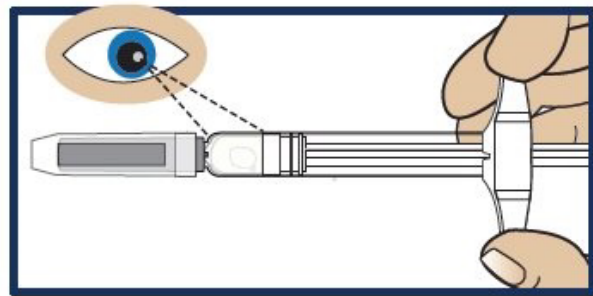
Do not use this medicine or inject if the liquid is discoloured, contains lumps, flakes, or particles.

Do not inject if solution is not visible in the syringe.

After injection, call for emergency medical help right away.

Each syringe contains a single dose of glucagon and cannot be reused.

Figure 2



Inject

Choose injection site and expose bare skin.

Choose the lower abdomen, outer thigh, or outer upper arm for your injection site (see Figure 3).

Remove any clothing covering the injection site (see Figure 4). The injection must be performed straight into the skin.

Important:

Do not inject through clothing.

Figure 3

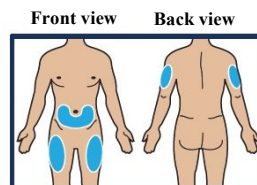


Figure 4



Pull the needle cap straight off of the syringe (see Figure 5).

Important:

Do not put your thumb, fingers, or hand on the needle to help prevent accidental needle sticks.

Figure 5



Pinch, insert, and push to start injection

Pinch the skin directly around the chosen injection site and keep pinching for the entire injection (see Figure 6). This is recommended to make sure a subcutaneous (under the skin) injection is given and to prevent injection into the muscle.

Without touching the plunger, insert the needle into the skin at the injection site at a 90-degree angle (see Figure 7).

Push the plunger down as far as it will go to inject all of the liquid medicine into the skin (see Figure 8). Inject the medicine very fast to help decrease the pain.

Lift the syringe straight up from the injection site.

Important:

Do not aspirate (pull back on plunger rod) after inserting the needle.

Do not lift up Ogluo until the injection is complete. Do not recap the syringe.

Figure 6



Figure 7

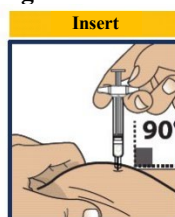
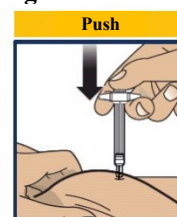


Figure 8



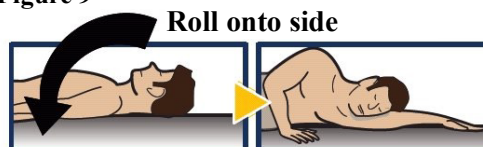
Assist

Turn patient onto side

When an unconscious person wakes up, he or she may be sick (vomit). If the patient is unconscious, turn them on their side to prevent choking (see Figure 9).

Call for emergency medical help right after Ogluo has been injected. When the patient has responded to the treatment, give him/her a fast-acting source of sugar, such as fruit juice or a sugar-containing carbonated drink to prevent the recurrence of low blood sugar. If the patient does not respond within 15 minutes, an additional dose of Ogluo from a new device may be administered while waiting for emergency assistance.

Figure 9



How much to use

This medicine contains either 0.5 mg or 1 mg of the active substance in a fixed dose of medicine. You will be prescribed the correct strength (dose) of medicine for your own personal use.

The recommended dose for adults, adolescents, and children is shown in the table below. For children under 6 years, the recommended dose will depend on how much they weigh.

Age	Weight	Recommended dose of Ogluo
Children, ages 2 years to under 6 years	Less than 25 kg	0.5 mg
Children, ages 2 years to under 6 years	More than or equal to 25 kg	1 mg
Adults and adolescents, 6 years and over	Not Applicable	1 mg

After using this medicine, eat as soon as possible to prevent the recurrence of low blood sugar. Take a fast-acting source of sugar, such as fruit juice or a sugar-containing carbonated drink.

If you use more Ogluo than you should

Too much medicine may make you feel sick (nausea) or cause you to be sick (vomit). Specific treatment is not usually necessary.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor or a healthcare professional immediately if you notice any of the following serious side effects:

Very rare (may affect up to 1 in 10,000 people)

- allergic reaction – signs may include wheezing, sweating, rapid heartbeat, rash, swollen face (i.e, swelling of the face, lips, tongue, and throat which may cause difficulty in swallowing or breathing), or collapse. Allergic reaction has not been reported with Ogluo, but has been seen in other injectable glucagon medicines. You should seek help urgently if you experience symptoms of an allergic reaction.

Other side effects may include

Very common (may affect more than 1 in 10 people)

- feeling sick (nausea)
- being sick (vomiting)

Common (may affect up to 1 in 10 people)

- headache
- fast heartbeat (tachycardia)
- discomfort or a reaction at the site of injection
- injection site oedema (swelling)
- diarrhoea

Uncommon (may affect up to 1 in 100 people)

- abdominal pain
- injection site bruising
- injection site erythema (redness)

Additional side effects in children

Common (may affect up to 1 in 10 people)

- hyperglycaemia
- abdominal pain
- urticaria (swelling/redness)
- head injury
- dizziness

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ogluo

Do not use this medicine after the expiry date which is stated on the syringe, pouch, and carton. The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children.

This medicine should not be stored above 25°C.

Do not refrigerate or freeze. Do not store below 15°C.

Store in the foil pouch before use to protect from light and moisture.

Do not use this medicine if you notice the solution is discoloured or contains particulate matter.

Do not throw away any medicines via household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ogluo contains

- The active substance in Ogluo is glucagon.
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Each pre-filled syringe contains 1 mg glucagon in 0.2 mL.
- The other ingredients are trehalose dihydrate, dimethyl sulfoxide (DMSO), sulfuric acid, and water for injections.

What Ogluo looks like and the contents of the pack

Ogluo is a clear, colourless to pale yellow solution. It is produced in a ready-to-use, pre-filled, single-dose syringe, containing either 0.5 mg or 1 mg of glucagon. Each product is individually packaged in a foil pouch. A full list of the available Ogluo products is provided below.

- Ogluo 0.5 mg solution for injection in pre-filled syringe, pack of 1 or 2 single-dose pre-filled syringes.

- Ogluo 1 mg solution for injection in pre-filled syringe, pack of 1 or 2 single-dose pre-filled syringes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Tetris Pharma B.V
Bargelaan 200
Element Offices
2333 CW Leiden
Netherlands

Manufacturer:

AcertiPharma B.V.,
Boschstraat 51,
Breda, 4811 GC,
Netherlands

Manufacturing Packaging Farmaca (MPF) B.V.
Neptunus 12
Heerenveen, 8448CN
Netherlands

This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
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