

# INSTRUCTIONS FOR USE:

## Rapilose OGTT Solution

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### 1. What is Rapilose OGTT Solution and what is it used for?

**Rapilose OGTT Oral Solution** is a transparent, orange-flavoured, non-viscous oral solution with a pH of approximately pH 3.0.

**Rapilose** has been specifically formulated and packaged by Penlan Healthcare to provide the most simple and cost-effective way to deliver an Oral Glucose Tolerance Test ("OGTT") in compliance with WHO guidelines whether in a hospital, doctor's surgery or in-store pharmacy. Care has been taken to provide a pleasant tasting solution, which minimises and standardises the amount to be consumed by the patient. The ready-mixed pouch has a long shelf life, minimal packaging and easily transportable format. The pleasant orange flavour is easy-to-drink and suitable for paediatric applications and patients who struggle to consume carbonated beverages.

### 2. What are the benefits of Rapilose OGTT Solution?

**Rapilose** is specifically formulated to comply with WHO OGTT guidelines and is applicable to the entire EU.

- Every batch of **Rapilose** is manufactured and specifically titrated to deliver exactly 75mg of anhydrous glucose.
- **Rapilose** has been designed to be the recommended quantity (300ml) required to be consumed as part of the OGTT.
- **Rapilose** is in a ready-to-drink format with no mixing or measuring required, facilitating in-community testing.
- **Rapilose** has a pleasant orange flavour containing natural and artificial flavourings

- **Rapilose** does not contain any colouring additives
- **Rapilose** is non-carbonated.
- **Rapilose** is gluten, lactose, fat and alcohol free.
- **Rapilose** has a long shelf life and is easy to store.
- **Rapilose** is supplied in low volume packaging which is fully recyclable.
- **Rapilose** is a cost effective, time saving alternative, particularly when compared on a fully costed basis, i.e. including all the costs of preparation, storage and dispensing.
- **Rapilose** can be easily adjusted to paediatric applications based on body mass.
- **Rapilose** is a quality product developed and manufactured in the EU to European food and nutritional regulations.

### 3. Before you use Rapilose OGTT Solution

#### Patient Preparation

The test should only be carried out on patients who are on a stable diet, at a constant weight and with no acute illness. The patient should have maintained an adequate carbohydrate intake (125-150 g/day) for three days prior to the scheduled OGTT. The patient is required to fast overnight before the test for a minimum nine hours with nothing by mouth except water (no medications, caffeine or tobacco).

Other factors can weaken the diagnostic power of the test and should be avoided as far as possible. These include severe inactivity over the preceding weeks, bed rest for several days, medical or surgical stress, fear of venepuncture, smoking during the test and certain drugs including thiazides,  $\beta$ -blockers, glucocorticoids and phenytoin.

### 4. How to use Rapilose OGTT Solution

#### Test Procedure

The test should be administered in the morning and the patient must rest during the test period.

**(a)** Confirm the patient has fasted for a minimum nine hours.

**(b)** Take a 2ml fasting blood sample into a fluoride/oxalate tube and mix well. Check that the tube is correctly labelled with patient's details and the sample time. The fluoride inhibits the metabolism of glucose by the red blood cells, but only if the tube is well mixed. Otherwise a falsely low result may be found by the time the sample is measured.

(c) Provide the patient with the RapiLOSE pouch (equivalent to 75g of anhydrous glucose in a ready-to-drink format). The solution should be consumed within five minutes. The patient should not be allowed to leave the department premises and should rest quietly without exercise, food, drink or smoking. Sips of water are allowed. For children the dose is 1.75g of glucose per kg of body weight to a maximum 75g.

(d) Two hours after the RapiLOSE pouch was consumed take a second 2ml blood sample into a fluoride/oxalate tube and mix well. Check the tube is labelled with the patient's details and correct sample time and send to the laboratory together with the initial sample requesting an OGTT.

(e) The patient should be advised to have something to eat and drink before leaving the department.

### Dosage

**Adults (including the elderly):** 300ml to be consumed over a period of 5-10 minutes as part of an oral glucose tolerance test.

**Children:** For children weighing less than 43kg the dosage should be reduced based on child's body mass; the dose is 7ml of solution per kg of body weight up to a maximum 300ml.

**Elderly:** There is no dose modification required for this age group.

### Protocol for OGTT in Ante-Natal Patients

The same considerations and protocol apply as above. However, in pregnancy, gestational diabetes is confirmed if the two hour glucose level is 7.8 mmol/l or more.

Be aware, some pregnant women are likely to vomit if asked to consume liquids quickly.

### How should oral glucose tolerance test results be interpreted?

Test results should be interpreted in accordance with venous plasma glucose levels as specified by the World Health Organisation and International Diabetes Federation set out in the table below.

| Venous Plasma Glucose Levels |                       |      |                                   |      |                                   |      |                                       |       |
|------------------------------|-----------------------|------|-----------------------------------|------|-----------------------------------|------|---------------------------------------|-------|
| Diagnosis                    | Normal                |      | Impaired Fasting Glycaemia (IFG)* |      | Impaired Glucose Tolerance (IGT)* |      | Diabetes Mellitus (DM)                |       |
|                              | Fasting               | 2hrs | Fasting                           | 2hrs | Fasting                           | 2hrs | Fasting                               | 2hrs  |
| Venous Plasma (mmol/l)       | <6.1                  | <7.8 | ≥6.1 & <7.0                       | <7.8 | <7.0                              | ≥7.8 | ≥7.0                                  | ≥11.1 |
| (mg/dl)                      | <110                  | <140 | ≥110 & <126                       | <140 | <126                              | ≥140 | ≥126                                  | ≥200  |
| Management                   | No follow-up required |      | Annual fasting plasma glucose     |      | Annual fasting plasma glucose     |      | Treat according to standard protocols |       |

## 5. Possible Side Effects

### Pregnancy and Lactation

This product is safe to use in pregnancy and with breast feeding mothers

### Allergies

RapiLOSE is gluten, lactose and alcohol free

## 6. How to store RapiLOSE OGTT Solution

What is the shelf-life for **RapiLOSE OGTT Solution** and are there any special storage conditions?

When stored unopened at room temperature, **RapiLOSE OGTT Solution** has a 24 month shelf-life.

After opening keep refrigerated; use within four days.

Store below 25°C

## 7. Ingredients

Each 300ml RapiLOSE pouch contains the following ingredients: water, glucose syrup, glucose monohydrate, flavouring, acidity regulator (citric acid), preservatives (potassium sorbate, sodium benzoate).

## 8. Nutritional Information

Each 300ml RapiLOSE pouch has the following nutritional values:

|                 | Per 100ml     | Per 300ml       |
|-----------------|---------------|-----------------|
| Energy          | 399kj/ 95kcal | 1198kj/ 286kcal |
| Protein         | 0g            | 0g              |
| Carbohydrates   | 23.8g         | 71.5g           |
| Of which sugars | 16.8g         | 50.3g           |
| Fat             | traces        | traces          |
| Fibre           | traces        | traces          |
| Sodium          | 0.001g        | 0.004g          |

