PRODUCT DATA SHEET

1. NAME OF THE PRODUCT

Rapilose OGTT Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per pouch

300ml solution contains 75g glucose

For a full list of ingredients see section 6.1

3. PRODUCT FORM

Rapilose OGTT Oral Solution is a transparent, acidic non-viscous oral solution with a pH of approximately pH 3.0

4. PRODUCT USE

4.1 INDICATIONS

Oral administration of 75g of anhydrous glucose in a ready-to-drink format as recommended in accordance with the World Health Organisation oral glucose tolerance test guidelines

4.2 HOW TO USE

For oral consumption only

Rapilose OGTT is ready to drink and can be taken diluted or undiluted

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: no dose modification required for this age group

4.3 CONTRAINDICATIONS

Hypersensitivity to any of the ingredients

Product contains 75g anhydrous glucose

4.4 PREGNANCY & LACTATION

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

5 PROPERTIES

Delivers the equivalent of 75g of anhydrous glucose in accordance with the World Health Organisation oral glucose tolerance test guidelines

6. NUTRITIONAL PARTICULARS

6.1 LIST OF INGREDIENTS

Water Glucose syrup Glucose monohydrate Orange (artificial and natural) flavouring Citric acid (acidity regulator) Potassium sorbate (preservative) Sodium benzoate (preservative)

6.2 NUTRITIONAL INFORMATION

Each pouch has the following nutritional values:

Content	Per 100ml	Per 300ml
Energy	399kJ /95 kcal	1198kJ / 286kcal
Protein	Og	Og
Carbohydrates	23.8g	71.5g
of which Sugars	16.8g	50.3g
Fat	traces	traces
Fibre	traces	traces
Sodium	0.001g	0.004g

Rapilose OGTT Solution contains less than 150mg per 300ml of potassium.

6.3 INCOMPATIBILITIES

Not applicable

6.4 SHELF LIFE

24 months

After opening keep refrigerated; use within three days

6.5 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C

6.6 NATURE AND CONTENTS OF CONTAINER

Aluminium foil pouch with moulded polypropylene cap having a tamper evident strip

PRODUCT DATA SHEET (Continued)

Pack size is 300ml

6.7 SPECIAL PRECAUTIONS FOR HANDLING AND OTHER PRECAUTIONS

No special requirements

6.8 PRODUCT CERTIFICATION

Manufactured in the Netherlands in compliance with all relevant UK and EU legislation

7 PRODUCT SALES, MARKETING AND DISTRIBUTION

7.1 PRODUCT PRODUCED AND MARKETED BY

Penlan Healthcare Limited 5 The Heights Weybridge KT13 ONY United Kingdom

7.2 PRODUCT SOLD & DISTRIBUTED BY

Galen Ltd Seagoe Industrial Estate Craigavon BT63 5UA United Kingdom

8 TEXT AND TEXT REVISIONS DATES

8.1 DATE OF TEXT

July 2011

8.2 DATE OF LATEST TEXT REVISION

December 2022