Lancashire Teaching Hospitals NHS Foundation Trust
Pharmacy Manufacturing Unit
Preston Pharmaceuticals

Paracetamol Oral Suspension (RPH Formula) 200mL

Synonyms:
Paracetamol Mucilage
Paracetamol suspension – Christie formula

Product identifier:
ZNB062R
(for orders)

Product code:
E 0239

Product Profile Part A: SPECIFICATION

Form: Oral Suspension
Strength: 1g in 10mL

Summary information
C of A available ✓
PIL available x
Label available ✓
Product image available: ✓
Alcohol Free x
Colour Free ✓
Preservative free x
Sugar free ✓
TSE/BSE statement ✓
Shelf life validated ✓
Shelf life: 9 months from manufacture
Opened shelf life: 28 days

Storage: Below 25°C

Physical Characteristics

Weight:	317g
Height:	13.2 cm
Width:	5.5 cm
Depth:	5.5 cm
Pack size:	200 mL

Container: 200mL Alpha glass bottle
Closure: 28mm child resistant tamper evident
Physical appearance: White, viscous suspension
Flavour: None (Sweetened)
Stability reference: Full in house testing Data on file.
Quality criteria: Full QC testing prior to release
Fill limits + / - 5%
Outer pack: Cardboard boxes
Number of containers per outer: 10

Preston Pharmaceuticals
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital,
Fulwood, Preston, PR2 9HT.

prestonpharmaceuticals@lthtr.nhs.uk

MS Licence number: MS 21327/01

Country of Origin: UK

Telephone: 01772 523617
Fax : 01772 523645

www.lancsteachinghospitals.nhs.uk/preston-pharmaceuticals

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Outline Manufacture Process:
Classical manufacture from first principles.
Produced by mechanical mixing of ingredients following a validated process
Packed using peristaltic pump
Capped and labelled by hand

Ingredients:
Paracetamol
Xanthan gum
Methylhydroxybenzoate / Propylhydroxybenzoate
Saccharin sodium
Ethanol
Citric acid / Sodium citrate
Water

Sample container label:
Label code RP1879E

SHAKE WELL BEFORE USE	200mL

PARACETAMOL ORAL SUSPENSION
1g in 10mL (RPH Formula)

Each 10mL contains: Paracetamol Ph.Eur. 1g. Also Contains: Xanthan Gum Ph.Eur., Methylhydroxybenzoate Ph.Eur., Propylhydroxybenzoate Ph.Eur., Saccharin Sodium BP, Ethanol Ph.Eur., Citric Acid Ph.Eur., Sodium Citrate Ph.Eur. and Water for Irrigation.

Do NOT take more than FOUR doses within 24 hours

Do NOT take with any other Paracetamol containing products. Immediate medical advice should be sought in the event of an overdose even if you feel well.

Use within 28 days of opening. Date opened:.....

NAME ..... DATE .....

KEEP OUT OF REACH AND SIGHT OF CHILDREN **STORE BELOW 25°C**

BATCH NUMBER Vvvvvv	Preston Pharmaceuticals	MS 21327/01
USE BEFORE Vwvwww	Royal Preston Hospital Preston PR2 9HT	RP1879F

Sample outer box label:
Label code: RP1880D

10 x 200mL
PARACETAMOL ORAL SUSPENSION
(RPH Formula)
1g in 10mL

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN
STORE BELOW 25°C

BATCH NUMBER Vvvvvvvv

USE BEFORE Vvvvvvvv

PRESTON PHARMACEUTICALS MS: 21327/01
ROYAL PRESTON HOSPITAL
PRESTON PR2 9HT RP1880C

The Human Medicines Regulations 2012 requires that medicinal products are licensed before they are marketed in the UK. However, some patients may have special clinical needs that cannot be met by licensed medicinal products. So that these special needs may be met, in Regulation 167 the law allows manufacture and supply of unlicensed medicinal products (commonly known 'specials') subject to the following conditions:

1) there is a bona fide unsolicited order,
2) the product is manufactured and assembled in accordance with the specification of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber registered in the UK,
3) the product is for use by their individual patients on their direct personal responsibility.

Responsibility for deciding whether an individual patient has "special needs" which a licensed product cannot meet is a matter for the prescriber responsible for the patient's care.

The MHRA expects manufacturers, importers and distributors of unlicensed medicines to obtain documentary evidence of this special need.
Responsibility for the use of an unlicensed medicine and the liability for any consequences rest with the prescriber. In the event of adverse reactions, the prescriber may be called upon to justify their actions. The manufacturers will not be held accountable unless the medicine is proven to be defective in some way.