LACTULOSE 3.3G/5ML ORAL SOLUTION
PL 10321/0002

UKPAR

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LAY SUMMARY

The MHRA granted Resolution Chemicals Ltd a Marketing Authorisation (licence) for the medicinal product Lactulose 3.3g/5ml Oral Solution (PL 10321/0002). This medicine is available through pharmacies (P) for the treatment of chronic constipation and hepatic encephalopathy.

Lactulose 3.3g/5ml Oral Solution contains the active ingredient lactulose which is a laxative.

The test product was considered to be equivalent to the original product Duphalac (Solvay Healthcare Ltd) based on the data submitted.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of taking Lactulose 3.3g/5ml Oral Solution outweigh the risks, hence a Marketing Authorisation has been granted.
LACTULOSE 3.3G/5ML ORAL SOLUTION
PL 10321/0002

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a Marketing Authorisation for the medicinal product Lactulose 3.3g/5ml Oral Solution to Resolution Chemicals Ltd on 26 June 2007. This product is available through pharmacies.

The application was submitted as an abridged application according to Article 10.1 of Directive 2001/83/EC as amended, claiming to be a generic product of Duphalac (Solvay Healthcare Ltd). The reference product has been authorised in the UK since March 1988 and so the 10-year period of data exclusivity has expired.

The product contains the active ingredient lactulose and is indicated for the treatment of constipation and hepatic encephalopathy (hepatic coma).

Lactulose is an osmotic laxative used to treat constipation by increasing faecal bulk and stimulating peristalsis after it is broken down by colonic bacteria. Lactulose is used to treat hepatic encephalopathy by reducing the pH of the colon causing ammonia to form in the colon, thereby reducing blood-ammonia concentrations.

No bioequivalence study has been performed. The product can be considered exempt from this requirement due to the nature of the formulation.
PHARMACEUTICAL ASSESSMENT

COMPOSITION

The product is formulated as an aqueous solution containing 66% w/v of the active pharmaceutical ingredient lactulose. There are no excipients present.

Lactulose 3.3g/5ml Oral Solution is presented in HDPE bottles with white HDPE tamper evident screw caps in packs of 200ml, 300ml, 500ml, 1000ml and 5000ml of solution.

DRUG SUBSTANCE

Lactulose

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specifications are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

The applicant has provided a declaration stating that the lactose used in the manufacture of lactulose is derived from milk sourced from healthy animals under the same conditions as those for human consumption.

An appropriate specification based on the European Pharmacopoeia monograph is provided for lactulose.

Analytical methods have been validated and are satisfactory for ensuring compliance with the relevant specifications.

Batch analysis data are provided for seven batches and comply with the proposed specification.

Lactulose is stored in appropriate packaging.

Stability data have been generated supporting a retest period of 4 years when stored in the proposed packaging below 25°C. A warning is also included to not refrigerate or freeze the material.

DRUG PRODUCT

Other ingredients

The water used for the aqueous solution is potable water, but it is purified during the manufacturing process to a quality consistent with that of purified water that meets the European Pharmacopoeia standard.

Impurity profiles

A comparison of the impurity profiles of two batches of product with that of the reference product was provided. This data was supplemented with comparative batch
analysis data for an additional five batches. The results indicate that there were no significant differences between the test and reference products.

Manufacture
A full description and a detailed flow-chart of the manufacturing method including in-process control steps has been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out for all pack sizes. The results are satisfactory. Additional validation data will be supplied on the first three commercial batches when available.

Finished product specification
The proposed finished product specification is acceptable and the analytical methods used have been suitably validated. Batch analysis data have demonstrated compliance with the proposed release specification. Suitable reference standards were used.

Container Closure System
Satisfactory specifications and certificates of analysis have been provided for the packaging components. All primary product packaging complies with EU legislation regarding contact with food.

Stability
Finished product stability data support the proposed shelf-life of 2 years (6 months in-use) with storage conditions “Do not store above 25°C, Do not refrigerate or freeze.”

Bioequivalence/bioavailability
A bioequivalence study was not required for this type of product.

SPC, PIL and Labels
The SPC and labels are pharmaceutically acceptable.

A patient information leaflet (PIL) has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

CONCLUSION
The proposed product has been shown to be a generic product of the reference product and has met the requirements with respect to qualitative and quantitative content of the active substance, pharmaceutical form and composition. Similar impurity profiles have been demonstrated for the proposed and reference product.

It is recommended that a Marketing Authorisation should be granted for this application.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.
CLINICAL ASSESSMENT

No clinical data have been supplied with this application and none are required for a formulation of this type.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The important quality characteristics of Lactulose 3.3g/5ml Oral Solution are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type.

EFFICACY
The applicant’s Lactulose 3.3g/5ml Oral Solution has been shown to be a generic product of Duphalac (Solvay Healthcare Ltd).

No new or unexpected safety concerns arise from this application.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The risk benefit is, therefore, considered to be positive.
LACTULOSE 3.3G/5ML ORAL SOLUTION
PL 10321/0002

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Marketing Authorisation application on 30 June 2005.

2 Following standard checks and communication with the applicant, the MHRA considered the application valid on 14 September 2005.

3 Following assessment of the application, the MHRA requested further information relating to the quality dossier on 08 May 2006 and 02 January 2007.

4 The applicant responded to the MHRA’s requests, providing further information on 24 October 2006, 05 February 2007 and 26 April 2007 for the quality sections.

5 The application was determined on 26 June 2007.
# LACTULOSE 3.3G/5ML ORAL SOLUTION
## PL 10321/0002

## STEPS TAKEN AFTER AUTHORISATION – SUMMARY

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
</tr>
</thead>
</table>


SUMMARY OF PRODUCT CHARACTERISTICS

1  NAME OF THE MEDICINAL PRODUCT

Lactulose 3.3g /5ml Oral Solution

2  QUALITATIVE AND QUANTITATIVE COMPOSITION

5ml of Lactulose solution contains 3.3 g of Lactulose
Each 5 ml also contains not more than 0.53g of Galactose and not more than 0.40g of Lactose
For excipients, see 6.1.

3  PHARMACEUTICAL FORM

Oral Solution
Clear, colourless or pale brownish yellow liquid’

4  CLINICAL PARTICULARS

4.1  Therapeutic indications

For treatment of constipation and hepatic encephalopathy (hepatic coma).

4.2  Posology and method of administration

Route of administration: Oral
Initial dosage for constipation: Adults – 15ml twice daily
Children 5 to 10 years – 10ml twice daily
Children under 5 years – 5ml twice daily
Babies under 1 year – 2.5ml twice daily
Lactulose may be taken with water or fruit juice.

Initial dosage for hepatic encephalopathy:
Adults (including the elderly) – 30 to 50ml three times daily
Children – no dosage recommendations for this indication.

A doctor may wish to change these initial doses as ideally two or three soft stools should be produced daily.

4.3 Contraindications

Lactulose Liquid should not be given to patients with gastro-intestinal obstruction or galactosaemia.

4.4 Special warnings and precautions for use

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Because of the physiological mode of action of Lactulose Liquid Ph. Eur it may take up to 48 hours before effects are obtained. In addition there is a carry-over effect which may enable the patient to reduce the effective dose gradually over a period of time.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Reports on the clinical experience of lactulose and data from animal reproduction studies have not revealed any increase in embryotoxic hazard to the foetus if used in the recommended dose during pregnancy. If drug therapy is needed in pregnancy the use of this drug is acceptable.

4.7 Effects on ability to drive and use machines

None Known.

4.8 Undesirable effects

Side effects occur rarely. Cases of mild abdominal distension, cramps or flatulence have been reported following use of Lactulose Liquid Ph. Eur, but these effects generally subside after the initial stage of treatment.
High doses may provoke diarrhoea, nausea, vomiting, flatulence, or abdominal pain.

4.9 Overdose

No specific antidote. Symptomatic treatment should be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code A06 ADII

Lactulose is a synthetic disaccharide which is used in the treatment of constipation and in hepatic encephalopathy. Lactulose is broken down by colonic bacteria mainly into acetic and lactic acids which exert a local osmotic effect in the colon resulting in increased faecal bulk and stimulation of peristalsis. It may take up to 48 hours before an effect is obtained. When larger doses are given for hepatic encephalopathy the pH in the colon is reduced significantly by this acid production and the absorption of ammonium ions and other toxic nitrogenous compounds is decreased leading to a fall in blood-ammonia concentration.

5.2 Pharmacokinetic properties

Following oral administration, a negligible amount of Lactulose is absorbed in the gastro-intestinal tract. It passes essentially unchanged into the large intestine where it is metabolized by saccharolytic bacteria, forming simple organic acids such as lactic and acetic acid. Urinary excretion has been reported to be 3% or less.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.
6.2 **Incompatibilities**

None known.

6.3 **Shelf life**

2 years unopened
6 months after first opening

6.4 **Special precautions for storage**

Do not store above 25°C
Do not refrigerate or freeze

6.5 **Nature and contents of container**

HDPE bottle with white HDPE screw cap, containing 200, 300, 500, 1000 or 5000ml of Lactulose Solution.

6.6 **Special precautions for disposal**

None.

7 **MARKETING AUTHORISATION HOLDER**

Resolution Chemicals Ltd
Wedgwood Way
Stevenage
Herts
SG1 4QT
United Kingdom
8 MARKETING AUTHORISATION NUMBER(S)

PL 10321/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/06/2007

10 DATE OF REVISION OF THE TEXT

26/06/2007
UKPAR Lactulose 3.3g/5ml Oral Solution

PATIENT INFORMATION LEAFLET/LABEL

RESOLUTION CHEMICALS LTD

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lactulose 3.3g/5ml Oral Solution
(Active substance: Lactulose)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You must also read it again.
- If you have any questions, ask your doctor or pharmacist.
- This medicine may be prescribed for you. Do not pass it on to others.
- If you are unsure, even if the symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Lactulose Solution is and what it is used for
2. Before you take Lactulose Solution
3. How to take Lactulose Solution
4. Possible side effects
5. How to store Lactulose Solution
6. Further information

1. WHAT LACTULOSE SOLUTION IS AND WHAT IT IS USED FOR
Lactulose Solution belongs to a group of medicines called laxatives. It is used in the treatment of:

Chronic constipation:
- Constipation is a common complaint due to not enough roughage or fibre in the diet, dehydration, immobility, illness or stress. Sometimes constipation may be due to more serious reasons. You should consult your doctor if you suffer from constipation for a period of greater than 4 weeks.

2. BEFORE YOU TAKE LACTULOSE SOLUTION
Do not take Lactulose Solution if:
- you know that you are allergic (causing itching, redness of the skin or difficulty in breathing) to Lactulose Solution or any of the other ingredients of Lactulose Solution listed in Section 6 at the end of this leaflet;
- you are suffering from a blockage in your gut or intestine;
- you suffer from a rare inherited condition of the metabolism called galactosaemia (an increase in a sugar called galactose in the blood).

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines that you have obtained without a prescription.

3. HOW TO TAKE LACTULOSE SOLUTION
Lactulose Solution is for oral use only.
The effects of Lactulose may not be seen for up to 48 hours, therefore it is important to continue taking your medicine regularly.

To treat constipation:
The table below gives the starting doses of Lactulose Solution depending on your age. However, the dose may be adjusted by your doctor depending on your needs to have the desired effect.

<table>
<thead>
<tr>
<th>Group</th>
<th>Starting dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>15ml twice daily (3 x 5ml spoonful)</td>
</tr>
<tr>
<td>Children 5-10 years</td>
<td>10ml twice daily (2 x 5ml spoonful)</td>
</tr>
<tr>
<td>Children under 5 years</td>
<td>5ml twice daily (1 x 5ml spoonful)</td>
</tr>
<tr>
<td>Babies under 1 year</td>
<td>2.5ml twice daily (½ x 5ml spoonful)</td>
</tr>
</tbody>
</table>

(Dosage continues) To treat hepatic encephalopathy:
Higher doses of Lactulose Solution are required.

- Starting dose
  - Adults: 30-50ml three times daily (6-10 x 5ml spoonful)
  - Elderly as above
  - Children: not to be taken (Lactulose is not suitable for children with this condition)

Your doctor may adjust your dose until two or three soft stools are produced a day.

If you take more Lactulose Solution than you should:
Contact your nearest casualty department or tell your doctor or pharmacist straight away. Take this leaflet and any remaining solution with you so that the medical staff know exactly what you have taken.

If you forget to take Lactulose Solution:
If you forget to take a dose of Lactulose Solution, take it as soon as you remember. If it is almost time for your next dose though, do not double the dose — just carry on as before.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Lactulose Solution can cause side effects, although not everybody gets them. If any of these side effects become troublesome, stop taking the medicine and see your doctor as soon as possible.

The most common side effects probably affecting up to 1 in 10 people are: bloated stomach, excess wind or stomach cramps. You may suffer from these in the first few days of taking your medicine. These usually go away on continuation of your treatment.
If you are taking large doses of Lactulose Solution to treat hepatic encephalopathy you may also suffer from diarrhoea, nausea (feeling sick), vomiting (being sick), flatulence and stomach pain. If this is the case, tell your doctor as he can adjust your dose to obtain just two or three soft stools a day.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LACTULOSE SOLUTION

Keep out of the reach and sight of children.

Do not store above 25°C. Do not refrigerate or freeze. Do not use Lactulose Solution after the expiry date which is stated on the can or after EXP. The expiry date refers to the last day of that month.

Use within 6 months of first opening and discard any remaining solution.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Lactulose Solution contains

The active substance is Lactulose

The other ingredients are: Lactose and Galactose

What Lactulose Solution looks like and contents of the pack

Lactulose Solution is a clear, colourless or pale brownish yellow liquid. 5ml of Lactulose Solution contains 3.3g of Lactulose.

Each 5ml also contains not more than 0.53g of Galactose and not more than 0.40g of lactose.

Lactulose Solution is available in 250, 300, 500, 1000, 5000ml plastic bottles.

Marketing Authorisation Holder
Resolution Chemicals Ltd., Wedgewood Way, Stevenage Herts., SG1 4QT.

Manufacturer
Thorpe Laboratories Limited,
Enterprise Road, Golf Road Industrial Estate, Mablethorpe,
Lincolnshire, LN12 1NB.

This leaflet was last revised in February 2007.
UKPAR Lactulose 3.3g/5ml Oral Solution  
PL 10321/0002

PATIENT INFORMATION LEAFLET/LABEL  
ARROW GENERICS

PACKAGE LEAFLET: INFORMATION FOR THE USER
Lactulose 3.3g/5ml Oral Solution  
(Active substance: Lactulose)

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.
- It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Lactulose Solution is and what it is used for
2. Before you take Lactulose Solution
3. How to take Lactulose Solution
4. Possible side effects
5. How to store Lactulose Solution
6. Further information

1. WHAT LACTULOSE SOLUTION IS AND WHAT IT IS USED FOR
Lactulose Solution belongs to a group of medicines called laxatives. It is used in the treatment of:
Chronic (long term) constipation: Constipation is a common complaint often due to not enough roughage or fibre in the diet, dehydration, immobility, illness or stress. Sometimes constipation may be due to more serious reasons. You should consult your doctor if you have symptoms of chronic constipation for a period of greater than 4 weeks.

2. BEFORE YOU TAKE LACTULOSE SOLUTION
Do not take Lactulose Solution if:
- you know that you are allergic (causing itching, redness of the skin or difficulty in breathing) to Lactulose Solution or any of the other ingredients of Lactulose Solution listed in Section 6 at the end of this leaflet;
- you are suffering from a blockage in your gut or intestine;
- you suffer from a rare inherited condition of the metabolism called galactosaemia (an increase in a sugar called galactose in the blood).

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines that you have obtained without a prescription.

Taking Lactulose Solution with food and drink: Lactulose Solution may be taken with a drink such as water or fruit juice.

Pregnancy and breast-feeding
It is always best to avoid the use of medicines during pregnancy if possible. However, if it is safe to take Lactulose Solution during pregnancy and when breast-feeding, as long as you follow the dosage recommendations.

Driving and using machines
There should be no problems when taking Lactulose Solution.

Important information about some of the ingredients of Lactulose Solution: Lactulose Solution contains Lactose and Galactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicine.

3. HOW TO TAKE LACTULOSE SOLUTION
Lactulose Solution is for oral use only.
The effects of Lactulose may not be seen for up to 48 hours, therefore it is important to continue taking your medicine regularly.

To treat constipation:
The table below gives the starting doses of Lactulose Solution depending on your age. However, the dose may be adjusted by your doctor depending on your needs to the desired effect.

<table>
<thead>
<tr>
<th>Dose</th>
<th>Adults 15ml twice daily (3 x 5ml spoonful)</th>
<th>Children 5 to 10 years 10ml twice daily (2 x 5ml spoonful)</th>
<th>Children under 5 years 5ml twice daily (1 x 5ml spoonful)</th>
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<tbody>
<tr>
<td></td>
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<td>PTD</td>
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</tbody>
</table>

(Dosage continued) To treat hepatic encephalopathy:
Higher doses of Lactulose Solution are required.

Start dose
Adults 30-50ml three times daily (6-10 x 5ml spoonful)
Children not to be taken (lactulose is not suitable for children with this condition)
Your doctor may adjust your dose until two or three soft stools are produced a day.

If you take more Lactulose Solution than you should
Contact your nearest casualty department or tell your doctor or pharmacist straight away. Take this leaflet and any remaining solution with you so that the medical staff know exactly what you have taken.

If you forgot to take Lactulose Solution
If you forget to take a dose of Lactulose Solution, take it as soon as you remember. If it is almost time for your next dose though, do not double the dose - just carry on as before.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Lactulose Solution can cause side effects, although not everybody gets them. If any of these side effects become troublesome, stop taking the medicine and see your doctor as soon as possible.

The most common side effects probably affecting up to 1 in 10 people are bloated stomach, excess wind or stomach cramps. You may suffer from these in the first few days of taking your medicine. These usually go away on continuation of your treatment.
If you are taking large doses of Lactulose Solution to treat hepato-encephalopathy you may also suffer from diarrhoea, nausea (feeling sick), vomiting (being sick), flatulence and stomach pain. If this is the case, tell your doctor as he can adjust your dose to obtain just two or three soft stools a day.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LACTULOSE SOLUTION

Keep out of the reach and sight of children.

Do not store above 25°C. Do not refrigerate or freeze. Do not use Lactulose Solution after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Use within 6 months of first opening and discard any remaining solution. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Lactulose Solution contains
The active substance is Lactulose
The other ingredients are: Lactose and Galactose

What Lactulose Solution looks like and contents of the pack
Lactulose Solution is a clear, colourless or pale brownish yellow liquid. 5ml of Lactulose Solution contains 3.3g of Lactulose. Each 5ml also contains not more than 0.53g of Galactose and not more than 0.40g of lactose.

Lactulose Solution is available in 200, 300, 500, 1000, 5000ml plastic bottles.

Marketing Authorisation Holder
Resolution Chemicals Ltd., Wedgewood Way, Stevenage Herts., SG1 4QT.

Manufacturer
Therpe Laboratories Limited, Enterprise Road, Golf Road Industrial Estate, Mablethorpe, Lincolnshire, LN12 1AB.

This leaflet was last revised in February 2007
**UKPAR Lactulose 3.3g/5ml Oral Solution**

### LABELLING

**RESOLUTION CHEMICALS LTD**

**For oral use. Dosage for constipation:**
- Adults: 15ml twice a day.
- Children 6 to 10 years: 10ml twice daily.
- Children under 5 years: 5ml twice daily.
- Glucose or fructose diabetics: 2.5ml twice daily.
- or as directed by your doctor.

**Dosage for other conditions:**
- as directed by your doctor.
- Take with milk or fruit juice if required.
- Please read the package leaflet before use.
- Keep out of the reach and sight of children.

**StORAGE:**
- Do not store above 25°C. Do not refrigerate or freeze.
- Use within 6 months of first opening then discard.

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**Lactulose 3.3g/5ml Oral Solution**

**500 ml**

5ml of Lactulose Solution contains 3.3g of Lactulose. Each 5ml also contains not more than 0.55g of Galactose and not more than 0.62g of Lactose.

**MA Holder:** Resolution Chemicals Ltd., Wedgwood Way, Stevenage, Herts, SG1 4D7
LABELLING
ARROW GENERICS

For oral use. Dosage for constipation:-

Adults: 15ml twice daily
Children 5 to 12 years: 10ml twice daily
Children under 5 years: 5ml twice daily

With or as directed by your doctor.

Dosage for other conditions:-

As directed by your doctor.

Take with water or fruit juice if required.

Keep out of the reach and sight of children.

Expire:

Do not store above 25°C. Do not refrigerate or freeze.

Use within 6 months of first opening then discard.

Lactulose 3.3g/5ml Oral Solution

500 ml

5ml of Lactulose Solution contains 3.3g of Lactulose. Each 5ml also contains not more than 0.53g of Galactose and not more than 0.40g of Lactose.

PL 10321/0002

MA Holder: Resolution Chemicals Ltd., Wedgewood Way, Stevenage, Herts, SG1 4DT

Distributed by Arrow Generics Limited, Eastman Way, Stevenage, Herts, SG1 4SZ.