# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Lactulose Solution BP

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lactulose BP 3.4g/5ml

## 3 PHARMACEUTICAL FORM

Oral liquid

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Constipation, hepatic encephalopathy (portal systemic encephalopathy)

### 4.2 Posology and method of administration

For oral use

**Constipation**

| | | |
|---|---|---|
| Adults (including the elderly): | Initially 15ml twice daily | |
| Children: | 1-5 years | 5ml twice daily |
| | 5-10 years | 10ml twice daily |

If, after three days, symptoms persist or have worsened, a doctor should be consulted to establish a definitive diagnosis.

Dosage may vary depending on the condition. The above dosage serves as a guide. Eventually the dose should be adjusted, usually reduced to meet the need of the individual.

**Hepatic encephalopathy**

Adults (including the elderly): Initially 30 - 50ml three times daily; adjust dose to produce two or three soft stools daily.

Children: No dosage recommendations for this indication.

## 4.3 Contraindications

Where there is evidence of gastrointestinal obstruction and in patients who require a galactose-free diet.

Patients with known intolerance or hypersensitivity to lactulose or to any of the other constituents of the product.

Patients with undiagnosed abdominal symptoms.

Patients with abdominal pain, nausea and vomiting - unless advised by a doctor.

Patients with a sudden change in bowel habit that persists for more than two weeks.

Patients with rectal bleeding.

Patients who fail to defaecate following use of a laxative.

## 4.4 Special warnings and precautions for use

The product should be administered with care to patients who are intolerant to lactose. Due to the products physiological mode of action it may take up to 48 hours before effects are obtained, however the product does exhibit a “carry-over” effect which may enable the patient to reduce the dose gradually over a period of time.

Care should be exercised if treating patients who have diabetes mellitus with this product.

Excessive and prolonged use could result in diarrhoea, causing water and electrolyte loss. In this event, a physician should be consulted.

## 4.5 Interaction with other medicinal products and other forms of interaction

None stated.

### 4.6 Pregnancy and lactation

The product should only be administered on the advice of a physician during pregnancy and lactation. As with all medicines the potential benefits of therapy should be weighed against any possible risk to the foetus or neonate if used in pregnancy and lactation.

### 4.7 Effects on ability to drive and use machines

None stated.

### 4.8 Undesirable effects

In the event of diarrhoea, adequate fluid intake should be maintained during treatment and the dosage reduced to prevent loss of fluid and potassium and exacerbation of encephalopathy. The product may give rise temporarily to flatulence and abdominal cramping. Nausea and vomiting may occur following the ingestion of high doses.

### 4.9 Overdose

Patients should be given plenty of fluids. An anticholinergic preparation such as atropine methonitrate would help to offset the excessive intestinal motility.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically Acting Laxative ATC code: A06AD11.

The action of lactulose in treating constipation depends on the inability of the enzymes in the small intestine to hydrolyse the synthetic disaccharide, lactulose, into its component molecules of fructose and galactose. Therefore, as lactulose is virtually unabsorbed, it passes into the large bowel chemically unchanged and forms a substrate for commensal saccharolytic bacteria.

The resulting breakdown products, simple organic compounds like lactic acid and acetic acid, give rise to increased intracolonic osmotic pressure, with consequent

increased faecal bulk, and stimulate peristalsis. The growth of saccharolytic bacteria is favoured and the normal colonic flora restored. A soft stool is formed and normal bowel action encouraged without irritation or direct interference with the gut mucosa.

In patients with hepatic encephalopathy larger doses of lactulose are used; a significant reduction in the pH of the colonic contents results, which reduces markedly the formation and absorption of ammonium ions and other nitrogenous toxins into the portal circulation. Rapid decrements in blood ammonia concentration have been reported following lactulose treatment.

### 5.2 Pharmacokinetic properties

Following administration by mouth, lactulose is almost completely unabsorbed from the gastro-intestinal tract: It passes essentially unchanged into the large intestine where it is metabolised by saccharolytic bacteria with the formation of simple organic acids, mainly lactic acid and small amounts of acetic and formic acids. Urinary excretion of unchanged lactulose has been reported to be 3% or less.

### 5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Purified water

### 6.2 Incompatibilities

None stated

### 6.3 Shelf life

36 months unopened.

### 6.4 Special precautions for storage

Store at or below 20°C. Do not freeze.

### 6.5 Nature and contents of container

i) amber glass winchesters with polypropylene caps as closures (1L).

ii) opaque, high density polyethylene bottles (200, 300, 500ml).

### 6.6 Special precautions for disposal

Not applicable.

## 7 MARKETING AUTHORISATION HOLDER

Transdermal Limited
Merlin House
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## 8 MARKETING AUTHORISATION NUMBER(S)

PL 14308/0019

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/05/1997

## 10 DATE OF REVISION OF THE TEXT

06/02/2018