# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT
Lactulose Sandoz 670 mg/ml, stroop

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION
1ml contains 670 mg Lactulose (as lactulose liquid).

## 3 PHARMACEUTICAL FORM
Oral solution
Clear colourless to pale brownish yellow, viscous solution

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications
- Symptomatic treatment of constipation

### 4.2 Posology and method of administration

Posology

The lactulose solution may be administered diluted or undiluted. The dose should be titrated according to the clinical response. Lactulose may be given as a single daily dose or in two divided doses, using the measuring cup.
A single dose of lactulose should be swallowed in one and should not be kept in the mouth for an extended period of time.

The posology should be adjusted according to the individual needs of the patient. The starting dose can be adjusted after adequate treatment effect individually (maintenance dose). Several days (2-3 days) of treatment may be needed in some patients before adequate treatment effect occurs. In case of single daily dose, this should be taken at the same time of the day, e.g. during breakfast. During the therapy with laxatives it is recommended to drink sufficient amounts of fluids (1.5-2 l/day, equal to 6-8 glasses).

| | Starting dose (per day) | | Maintenance dose (per day) | |
|---|---|---|---|---|
| Adults and adolescents over 14 years | 15-45 ml | corresponding to 10-30 g lactulose | 15-30 ml | corresponding to 10-20 g lactulose |
| Children (7-14 years) | 15 ml | corresponding to 10 g lactulose | 10-15 ml | corresponding to 7-10 g lactulose |
| Children (1-6 years) | 5-10 ml | corresponding to 3-7 g lactulose | 5-10 ml | corresponding to 3-7 g lactulose |
| Infants under 1 year | up to 5 ml | corresponding to up to 3 g lactulose | up to 5 ml | corresponding to up to 3 g lactulose |

If diarrhoea occurs, the dosing regimen should be reduced.

Elderly patients and patients with renal or hepatic insufficiency
No special dose recommendations exist, since systemic exposure to lactulose is negligible.

**Duration of treatment**
The duration of treatment has to be adopted according to the symptoms.

## 4.3 Contraindications

- Hypersensitivity to the active substance.
- Galactosaemia.
- Gastrointestinal obstruction, digestive perforation or risk of digestive perforation (e.g. acute inflammatory bowel disease such as ulcerative colitis, Crohn's disease).

## 4.4 Special warnings and precautions for use

Consultation of a physician is advised in case of:
- painful abdominal symptoms of undetermined cause before the treatment is started
- insufficient therapeutic effect after several days.

Lactulose should be administered with care to patients who are intolerant to lactose.

The dose normally used in constipation should not pose a problem for diabetics.
This product contains lactose, galactose and small amounts of fructose. Therefore, patients with rare hereditary problems of galactose or fructose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.
For patients with gastro-cardiac syndrome (Roemheld syndrome) lactulose should only be taken after consultation of a physician. If symptoms like meteorism or bloating occur in such patients after lactulose intake, the dose should be reduced or the treatment should be discontinued.

Chronic use of unadjusted doses and misuse can lead to diarrhoea and disturbance of the electrolyte balance.

For elderly patients or patients that are in bad general condition and who take lactulose for a more than 6 months period, periodic control of electrolytes is indicated.

Paediatric population

Use of laxatives in children should be exceptional and under medical supervision. It should be taken into account that the defaecation reflex could be disturbed during the treatment with lactulose.

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

No interaction studies have been performed.
Lactulose may increase the loss of potassium induced by other medicinal products (e.g. thiazides, corticosteroids and amphothericin B). Concomitant use of cardiac glycosides can increase the effect of the glycosides through potassium deficiency.

## 4.6 Fertility, pregnancy and lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to lactulose is negligible.
Lactulose can be used during pregnancy (see section 5.3).

Breast-feeding

No effects on the breast-fed newborn/infant are anticipated, since the systemic exposure of the breast-feeding woman to lactulose is negligible.

Lactulose can be used during breast-feeding (see section 5.3).

Fertility
No effects are to be expected, since systemic exposure to lactulose is negligible.

## 4.7 Effects on ability to drive and use machines

Lactulose has no or negligible influence on the ability to drive and use machines.

## 4.8 Undesirable effects

Summary of the safety profile
Flatulence may occur during the first few days of treatment. As a rule it disappears after a couple of days. When doses higher than instructed are used, abdominal pain and diarrhoea may occur. In such a case the dose should be decreased.

List of adverse reactions
The following undesirable effects have been experienced with the below indicated frequencies in lactulose-treated patients in placebo-controlled clinical trials:

| | |
|---|---|
| Very common | (≥1/10); |
| Common | (≥1/100 to <1/10); |
| Uncommon | (≥1/1,000 to <1/100); |
| Rare | (≥1/10,000 to <1/1,000); |
| Very rare | (<1/10,000) |

Gastrointestinal disorders

| | |
|---|---|
| *Very common:* | Diarrhoea |
| *Common:* | Flatulence, abdominal pain, nausea and vomiting |

Immune system disorders

| | |
|---|---|
| *Not known* | hypersensitivity reactions |

Skin and subcutaneous tissue disorders

| | |
|---|---|
| *Not known* | Rash, pruritus, urticaria |

Investigations

| | |
|---|---|
| *Uncommon:* | Electrolyte imbalance due to diarrhoea |

Paediatric population
The safety profile in children is expected to be similar as in adults.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V*.

### 4.9 Overdose

If the dose is too high, the following may occur:
Symptom:
Diarrhoea and abdominal pain.

Treatment:
Cessation of treatment or dose reduction. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for constipation, Osmotically acting laxatives.
ATC code: A06A D11

In the colon lactulose is broken down by colonic bacteria into low molecular organic acids. These acids lead to a lowering of pH in the colonic lumen and via an osmotic effect to an increase of the volume of the colonic contents. These effects stimulate the peristalsis of the colon and return the consistency of the stools. The constipation is cleared and the physiological rhythm of the colon is reinstated.

Lactulose as a prebiotic substance strengthens the growth of *Bifidobacterium* and *Lactobacillus*, whereas *Clostridium* and *Escherichia coli* may be suppressed. This leads to a relief of constipation and so beneficially influences the host´s well-being and health.

### 5.2 Pharmacokinetic properties

Lactulose is poorly absorbed after oral administration and reaches the colon unchanged. There it is metabolised by the colonic bacterial flora. Metabolism is complete at doses up to 25-50 g or 40-75 ml; at higher doses, a proportion may be excreted unchanged.

### 5.3 Preclinical safety data

Preclinical data based on studies of single and repeated dose toxicity reveal no special hazards for humans. A long-term animal study does not give reference to tumorigenic potential. Lactulose was not teratogenic in mice, rats and rabbits. After oral administration systemic toxicity is not to be expected due to the pharmacological and pharmacokinetic properties of lactulose.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

None.

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

3 years
After first opening: 1 year

### 6.4 Special precautions for storage

Do not store above 25°C

### 6.5 Nature and contents of container

*NL/H/2325/001*
Brown PET bottles with polyethylene screw cap or child resistant polypropylene closure containing 100ml, 10 x 100 ml, 200ml, 250 ml, 300ml, 500 ml, 1000 ml
White PET bottles with polyethylene screw cap or child resistant polypropylene closure containing 100 ml, 200 ml, 300 ml, 500 ml, 1000 ml
Brown glass bottles with polyethylene screw cap containing 100ml, 200ml, 250 ml, 300ml, 500 ml, 1000 ml

*NL/H/2354/001*
Brown PET bottles with polyethylene screw cap or child resistant polypropylene closure containing 180ml and 200ml.

As measuring device a measuring cup (polyproylene) with filling marks at 5, 10, 15, 20, 25 and 30 ml is added

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

No special requirements.

## 7 MARKETING AUTHORISATION HOLDER

Sandoz B.V.
Hospitaaldreef 29
1315 RC Almere
Nederland

## 8 MARKETING AUTHORISATION NUMBER(S)

RVG 109595

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

Datum van eerste verlening van de vergunning: 24 september 2012
Datum van verlenging van de vergunning: 23 juni 2015

## 10 DATE OF REVISION OF THE TEXT

Laatste gedeeltelijke wijziging betreft rubriek 7: 8 februari 2024