PROFESSIONAL INFORMATION FOR
LAXETTE DRY AND LAXETTE SOLUTION

SCHEDULING STATUS **S0**

1. NAME OF THE MEDICINE

LAXETTE DRY (10 g, powder)

LAXETTE (3,3 g/5 mL, solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of LAXETTE DRY contains: 10 g lactulose.

Contains sugar: Lactulose 10 g per sachet.

Each 5 mL of LAXETTE contains: 3,3 g lactulose.

Contains sugar: Lactulose 3,3 g/ 5 mL.

For the full list of excipients, see **section 6.1**.

3. PHARMACEUTICAL FORM

LAXETTE DRY: A white crystalline powder.

LAXETTE SOLUTION: A colourless to brownish – yellow, clear, or not more than slightly opalescent solution. Miscible in water. A 10 % v/v solution is levorotatory.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Lactulose is indicated in the management of constipation, particularly in association with laxative habituation and in post-surgical and obstetric patients, as well as in children.

For the management of hyperammonaemia in patients with chronic hepatic encephalopathy, including stages of hepatic pre-coma and coma.

4.2 Posology and method of administration

Posology

An effect may only be obtained after 24 - 48 hours.

LAXETTE DRY:

Constipation:

Adults:

Initial dose: 10 to 30 g given daily as a single dose or in 2 divided doses for three (3) days.

Maintenance dose: Adjust according to the patient's needs.

Dosage may be increased to 40 g daily if there is no response, or should be decreased if diarrhoea occurs.

Children (7-14 years):

Usual dosage: 10 g taken daily.

Dosage should be adjusted according to individual response.

Children (1- 6 years):

Usual dosage: 5 to 10 g taken daily.

Dosage should be adjusted according to individual response.

Portal System Encephalopathy:

Initial dosage: 60 to 120 g given daily in 3 or 4 divided doses.

Maintenance dose: Dosage should be adjusted to produce 2 or 3 soft stools each day.

LAXETTE SOLUTION:

Constipation:

Initial dose should be taken for three (3) days in all age groups.

Adults:

Usual initial dose: 30 mL

Maintenance dose: 15 - 30 mL

Children (6 - 14 years):

Usual initial dose: 15 mL

Maintenance dose: 10 - 15 mL

Children (1 - 5 years):

Usual initial dose: 10 mL

Maintenance dose: 5 - 10 mL

Infants:

Usual initial dose: 5 mL

Maintenance dose: 2,5 - 5 mL

Portal System Encephalopathy:

Initial dose: 30 - 50 mL three times daily.

Subsequently adjust the dose to produce two or three soft stools daily.

Method of administration

LAXETTE DRY can be taken with drinks e.g., tea, coffee, fruit juice or milk, or with breakfast cereals.

Drink a full glass of liquid or more, with each dose of LAXETTE DRY.

4.3 Contraindications

- Patients with known hypersensitivity to Lactulose or to any of the excipients used in the formulation of LAXETTE (see **section 6.1**).
- Lactulose should not be administered to patients with abdominal obstruction, appendicitis, undiagnosed rectal bleeding, congestive heart failure or hypertension.
- Galactosaemia including patients on a low galactose diet should not use lactulose.
- Hyperosmotic laxatives should not be prescribed to colostomy or ileostomy patients.

4.4 Special warnings and precautions for use

If you have noticed a sudden change in bowel habits that has persisted for more than 2 weeks, consult a doctor before using this medication.

Care should be taken in patients with lactose intolerance or in diabetic patients, because of the presence of free lactose and galactose.

LAXETTE contains sugars such as fructose, galactose and lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take LAXETTE.

Laxatives should not be given to children younger than 6 years, unless prescribed by a medical practitioner.

4.5 Interaction with other medicinal products and other forms of interaction

Do not take within 2 hours of other medications.

Chronic use and the overuse of laxatives may interfere with the potassium retaining effects of potassium-sparing diuretics and may reduce serum potassium concentrations by promoting excessive potassium loss from the intestinal tract.

Blood glucose concentrations may be elevated after extended use of laxatives.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no data concerning the effect of LAXETTE in pregnant women.

Breastfeeding

There is no data concerning the effect of LAXETTE in breastfeeding.

Fertility:

There is no data concerning the effect of LAXETTE on fertility.

4.7 Effects on ability to drive and use machines

LAXETTE has no or negligible effect on the ability to drive or use machines.

4.8 Undesirable effects

The use of lactulose may result in abdominal discomfort associated with flatulence and cramps.

Nausea and vomiting have been reported, especially with higher doses.

Prolonged use or excessive dosage may cause diarrhoea, excessive loss of fluid and electrolytes, particularly potassium; and hypernatraemia.

Hepatic encephalopathy may also be exacerbated.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 and to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

Prolonged use or excessive dosage may result in diarrhoea, with excessive loss of water and electrolytes. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification

Pharmacotherapeutic group

A 11.5 Laxatives

Mechanism of action

Lactulose is a synthetic disaccharide of fructose and galactose. It reaches the colon unchanged where it is broken down by the colonic bacteria, mainly into lactic acid, which produces an osmotic effect in the colon, resulting in increased faecal bulk and stimulation of colonic peristalsis. The increased acid production of larger doses of lactulose, as given for hepatic encephalopathy, reduces the pH in the colon significantly and the absorption of ammonium ions and other toxic nitrogenous compounds are decreased, leading to a fall in blood-ammonium levels.

5.2 Pharmacokinetic properties

After oral administration, lactulose passes essentially unchanged into the large intestine where it is metabolised by saccharolytic bacteria into simple organic acids, mainly lactic acid and small amounts of formic and acetic acids. A small amount of lactulose is absorbed and is excreted unchanged in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Not applicable.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

- Store at or below 25 °C in well-closed containers.

6.5 Nature and contents of container

LAXETTE DRY is packed in a coated bleached kraft, LDPE, Aluminium foil and LDPE laminated sachets of 10 g each.

Pack sizes: 10's or 30's.

LAXETTE SOLUTION is packed in a amber glass medical rounds with White polypropylene caps with PVDC coated EXPE liners. Pack sizes of 150 mL and 500 mL.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

8. REGISTRATION NUMBER(S)

LAXETTE DRY: 36/11.5/0240

LAXETTE SOLUTION: 29/11.5/0609

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

LAXETTE DRY: 26 April 2003

LAXETTE SOLUTION: 03 October 1996

10. DATE OF REVISION OF THE TEXT

23 March 2023

Botswana

S3

LAXETTE DRY: BOT0700967

S2

LAXETTE: BOT0801175

Namibia

NS2

LAXETTE DRY: 10/11.5/0280

NS0

LAXETTE: 06/11.5/0297