SCHEDULING STATUS:
Not scheduled.

PROPRIETARY NAME (AND DOSAGE FORM):

LAXETTE DRY (Crystalline powder)

LAXETTE (Solution)

COMPOSITION:
Each sachet **LAXETTE DRY** contains 10 g lactulose.
Each 5 ml **LAXETTE** contains 3.3 g lactulose.

PHARMACOLOGICAL CLASSIFICATION:
A 11.5 Laxatives.

PHARMACOLOGICAL 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.

Pharmacokinetics:
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.

INDICATIONS:
LAXETTE 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.

LAXETTE is also indicated for the management of hyperammonaemia in patients with chronic hepatic encephalopathy, including stages of hepatic pre-coma and coma.

CONTRA-INDICATIONS:

- Hypersensitivity to lactulose or any component of the formulations.
- **LAXETTE** should not be administered to patients with abdominal obstruction, appendicitis, undiagnosed rectal bleeding, congestive heart failure or hypertension.
- Patients on a low galactose diet should not use **LAXETTE**.
- Hyperosmotic laxatives, such as **LAXETTE**, should not be prescribed to colostomy or ileostomy patients.

INTERACTIONS:
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.

DOSAGE AND DIRECTIONS FOR USE:
An effect may only be obtained after 24 – 48 hours.

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

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 to10 g taken daily.

Dosage should be adjusted according to individual response.

Portal system encephalopathy:
Drink a full glass of liquid or more, with each dose of LAXETTE DRY.

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

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

Dosage may vary widely depending on the severity of the condition. A relatively large initial dose should be followed by a smaller maintenance dose after the first 3 days of treatment. Only 1 dose daily needs to be taken, preferably after breakfast.

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 the dose should be adjusted to produce two or three soft stools per day.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Side-effects:
The use of **LAXETTE** may result in abdominal discomfort associated with bloating, flatulence and cramps. Increased thirst has occurred less frequently.

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.

Special Precautions:
Warning: 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.

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

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

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See **"SIDE-EFFECTS AND SPECIAL PRECAUTIONS"**.

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

IDENTIFICATION:
LAXETTE DRY: A white crystalline powder.
LAXETTE: A colourless to brownish-yellow solution with a sweet taste.

PRESENTATION:

LAXETTE DRY: 10 g sachets in packs of 10 or 30 per carton box.
LAXETTE: 150 ml and 500ml amber glass bottles or amber-coloured PET bottles with a white coloured cap.

STORAGE INSTRUCTIONS:
Store below 25ºC in well-closed containers.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:
LAXETTE DRY: 36/11.5/0240
LAXETTE: 29/11.5/0609

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:
MEDPRO PHARMACEUTICA (PTY) LTD
Rosen Heights, Pasita Street
Rosen Park, Bellville, 7530 RSA

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
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