PATIENT INFORMATION LEAFLET FOR

LAXETTE DRY AND LAXETTE SOLUTION

SCHEDULING STATUS : **S0**

LAXETTE DRY 10 g powder

LAXETTE 3,3 g/5 mL solution

Lactulose

LAXETTE DRY contains sugar: Lactulose 10 g per sachet

LAXETTE SOLUTION contains sugar: Lactulose 3,3 g per 5 mL

Read all of this leaflet carefully because it contains important information for you

LAXETTE is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use LAXETTE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LAXETTE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after several days.

What is in this leaflet

1. What LAXETTE is and what it is used for

LAXETTE (active) belongs to a class of medicine known as Laxative. It makes the stool softer and easier to pass, by drawing water into the bowel. It is not absorbed into your body.

LAXETTE is indicated for the treatment of constipation (infrequent bowel movements, hard and dry stools).

LAXETTE is used to treat hepatic encephalopathy (a liver disease causing confusion, tremor, decreased level of consciousness). Hepatic encephalopathy can lead to a hepatic coma.

2. What you need to know before you take LAXETTE

Do not take LAXETTE if you:

- are hypersensitive (allergic) to Lactulose or any of the other ingredients of LAXETTE (listed in **Section 6**).
- have a rare problem called 'galactosaemia'.
- Are on a low galactose diet
- have undiagnosed rectal bleeding
- have heart problems
- have high blood pressure
- have a blockage caused by anything else but normal constipation, gastrointestinal perforation or risk of perforation.

Warnings and precautions

Take special care with LAXETTE:

- if you suffer from unexplained tummy ache
- if you are unable to digest milk sugar (lactose intolerant)
- if you have diabetes

You should not take Lactulose if you suffer from:

- galactose or fructose intolerance
- total lactase deficiency
- glucose-galactose malabsorption

Children and adolescents

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

Other medicines and LAXETTE

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.

Do not take within 2 hours of other medications.

Long-term 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.

LAXETTE with food, drink and alcohol

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking LAXETTE**.**

Driving and using machinery

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

LAXETTE contains Lactulose

LAXETTE contains lactose/fructose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take LAXETTE, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take LAXETTE

Do not share medicines prescribed for you with any other person.

Always take LAXETTE exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

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 40g 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:

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.

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.

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

Your doctor will tell you how long your treatment with LAXETTE will last.

If you have the impression that the effect of LAXETTE is too strong or too weak, tell your doctor or pharmacist.

If you take more LAXETTE than you should

In the event of overdosage, consult your pharmacist or doctor. If neither is available, contact the nearest hospital or poison control center.

You may have diarrhoea, loss of electrolytes and abdominal pain.

If you forget to take LAXETTE

Do not take / receive a double dose to make up for forgotten individual doses.

If you stop taking LAXETTE

Not Applicable

4. Possible Side Effects

LAXETTE can have side effects

Not all side effects reported for LAXETTE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LAXETTE, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking LAXETTE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reactions, rash, itching, hives.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Diarrhoea
- flatulence (wind)
- nausea (feeling sick)
- vomiting
- abdominal pain
- electrolyte imbalance due to diarrhoea

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of LAXETTE.

5. How to store LAXETTE

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

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What LAXETTE contains

LAXETTE DRY: The active substance is Lactulose 10 g.

LAXETTE SOLUTION: The active substance is Lactulose 3.3 g/ 5 mL.

LAXETTE does not contain any excipients

What LAXETTE looks like and contents of the pack

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.

LAXETTE DRY: is presented 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 presented in a amber glass medical rounds with white polypropylene caps with PVDC coated EXPE liners. Pack sizes of 150 mL and 500 mL.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Registration number(s)

LAXETTE DRY: 36/11.5/0240

LAXETTE SOLUTION: 29/11.5/0609

Botswana

S3

LAXETTE DRY: BOT0700967

S2

LAXETTE: BOT0801175

Namibia

NS0

LAXETTE DRY: 10/11.5/0280

NS2

LAXETTE: 06/11.5/0297

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.