1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

LACSON 3,3 g per 5 ml syrup

Lactulose

Contains sugar: Lactulose 3,3 g

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share LACSON with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What LACSON is and what it is used for
2. What you need to know before you take/give your child LACSON
3. How to take/give your child LACSON
4. Possible side effects
5. How to store LACSON
6. Contents of the pack and other information

1. What LACSON is and what it is used for

LACSON belongs to a group of medicines called laxatives.

LACSON is used for the treatment of constipation (infrequent or difficult bowel movements, hard and dry stools), high blood pressure in the liver blood vessels (chronic portal hypertension), and liver disease causing confusion, tremor and decreased level of consciousness (hepatic encephalopathy).

2. What you need to know before you take/give your child LACSON

Do not take/give your child LACSON:

- If you are hypersensitive (allergic) to lactulose or any of the other ingredients of LACSON (listed in section 6).
- If you have rare hereditary conditions of galactose intolerance (galactosaemia), or if you are on a galactose-free diet.
- If you have a blockage in your bowel (intestinal obstruction), or tearing or wounds in your bowel (perforations), or if you are at risk of these tears/wounds.

Warnings and precautions

Take special care with LACSON:

- Long-term use of LACSON, misuse or taking too much of LACSON can cause diarrhoea and loss of minerals or salts from the body (see Possible side effects).
- The starting doses of LACSON are higher than the maintenance doses, and these starting does may cause nausea, stomach bloating (meteorism) or passing of wind (flatulence), but these effects are expected to disappear once the lower maintenance doses are reached (see Possible side effects).
- LACSON may affect your body's regular ability to pass stool (defaecation reflex).

- If you are diabetic (high levels of sugar in the blood), and you are being treated for hepatic encephalopathy, speak to your doctor.
- The dose used in the treatment of hepatic encephalopathy is usually much higher and may need to be taken into consideration for diabetics.
- The dose normally used in constipation should not pose a problem for diabetics.
- If your body is unable to digest milk sugar (lactose intolerant).

Children

There is no experience with LACSON in children for chronic portal hypertension and hepatic encephalopathy.

Use of medicines used to treat constipation (laxatives), such as LACSON, in children should be exceptional and used under the doctor, pharmacist or nurse's guidance.

Other medicines and LACSON

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Laxatives (medicines used to treat constipation). You should not use other laxatives while you are taking LACSON if you have high blood pressure in the liver blood vessels (chronic portal hypertension), and liver disease causing confusion, tremor and decreased level of consciousness (hepatic encephalopathy).

LACSON with food

LACSON should preferably be taken/given to your child after breakfast for constipation.

Pregnancy, breastfeeding and fertility

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

Driving and using machines

LACSON is not expected to influence your ability to drive or operate machinery.

It is not always possible to predict to what extent LACSON may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which LACSON affects you (see section 4).

LACSON contains fructose, galactose and lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LACSON.

3. How to take/give your child LACSON

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

Always take/give your child LACSON exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose of LACSON for constipation is one dose daily, preferably after breakfast.

Usual starting dose for constipation:

Adults: 30 ml (6 x 5 ml medicine measures).

Children (6 to 14 years): 15 ml (3 x 5 ml medicine measures).

Children (1 to 5 years): 10 ml (2 x 5 ml medicine measures).

Infants: 5 ml (1 x 5 ml medicine measure).

Maintenance dose for constipation:

Adults: 15 ml to 30 ml (3 to 6 x 5 ml medicine measures). ***Children (6 to 14 years):*** 10 ml to 15 ml (2 to 3 x 5 ml medicine measures).

Children (1 to 5 years): 5 ml to 10 ml (1 to 2 x 5 ml medicine measures).

Infants: 2,5 ml to 5 ml (½ to 1 x 5 ml medicine measures).

Initial dose for chronic portal hypertension and hepatic encephalopathy:

***Adults*:** 30 ml to 50 ml (6 to 10 medicine measures) three times daily.

Maintenance dose for chronic portal hypertension and hepatic encephalopathy:

***Adults*:** 30 ml to 45 ml (6 to 9 medicine measures) three or four times daily.

If you take/give your child more LACSON than you should

If you take/give your child more LACSON than you should, or if you/your child take LACSON for a long time, you/your child may get nauseous (feeling the urge to vomit), start vomiting or get diarrhoea (frequent/loose watery stools) with excessive loss of water and electrolytes (salts), especially potassium from your body.

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

If you forget to take/give your child LACSON

Do not take/give your child a double dose to make up for forgotten individual doses.

If you/your child have missed a dose of LACSON, take/give the child the dose that you/your child have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take/give several doses, contact your doctor without delay.

4. Possible side effects

LACSON can have side effects.

Not all side effects reported for LACSON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking/giving your child LACSON, please consult your healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LACSON. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Loose stools (diarrhoea), passing wind (flatulence), stomach pain, nausea, vomiting.

Less frequent side effects:

- Loss of minerals/salts from the body due to loose stools.

Side effects with an unknown frequency:

- Stomach discomfort, cramps, bloating (meteorism).

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: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of LACSON.

5. How to store LACSON

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 LACSON contains

The active substance is 3,3 g of lactulose per 5 ml.

There are no other ingredients.

Contains sugar: Lactulose 3,3 g

What LACSON looks like and contents of the pack

A colourless to brownish-yellow, clear or not more than slightly opalescent solution.

150 ml or 500 ml is packed into an amber, round, polyvinylchloride bottle and sealed with a white polypropylene screw cap.

150 ml or 500 ml is packed into an amber, round, PET bottle and sealed with a white polypropylene screw cap.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

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Hotline: 0800 122 912

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS0 04/11.5/0029

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