

This production drawing is the property of CCL Label A/S and may not be distributed to a third party without CCL Label A/S's written consent. You may only copy the material to persons within your organisation for which you hold full responsibility. You must at any time without delay return such material to CCL Label A/S when requested by CCL Label A/S in writing.

Customer name: **Fresenius Kabi Austria**
 Att: **Ivetta Vierlinger**
 Date: **29.11.2012**
 Proof: **5th**
 Approved:
 New proof required:
 Signature and date: _____

Dimensions: **55 x 183 mm**
 Braille: **Yes**
 No. of leaves: **8**
 Winding direction: **Outside 4**
 Die cutting number: **305**

CCL order no.: **I32284 (Gul 9276)**
 Art. no.: **V0054403/03**
 Name of label: **Lactulose Sandoz UK 300 ml**
 Customer Service ref: **Pia Hindkjær**
 Prepress ref: **MBR**

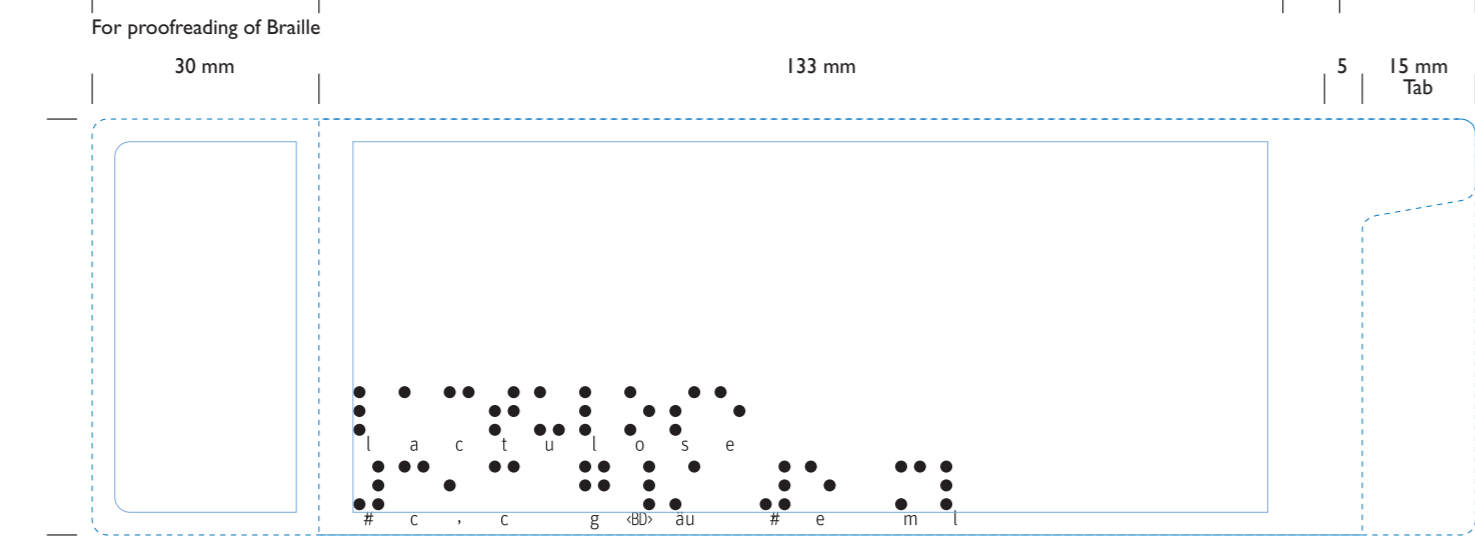
The colours on prime/sample print must not be considered as an exact version of the colours on the final print. Our printing department does not take the responsibility for mistakes, which are not corrected in the proof. Please note that some Braille characters can vary from country to country. Please check that all Braille characters are as requested.

Base label (Selfadhesive) 30 mm 127,5 mm 7,5 mm 18 mm Tab/Glue



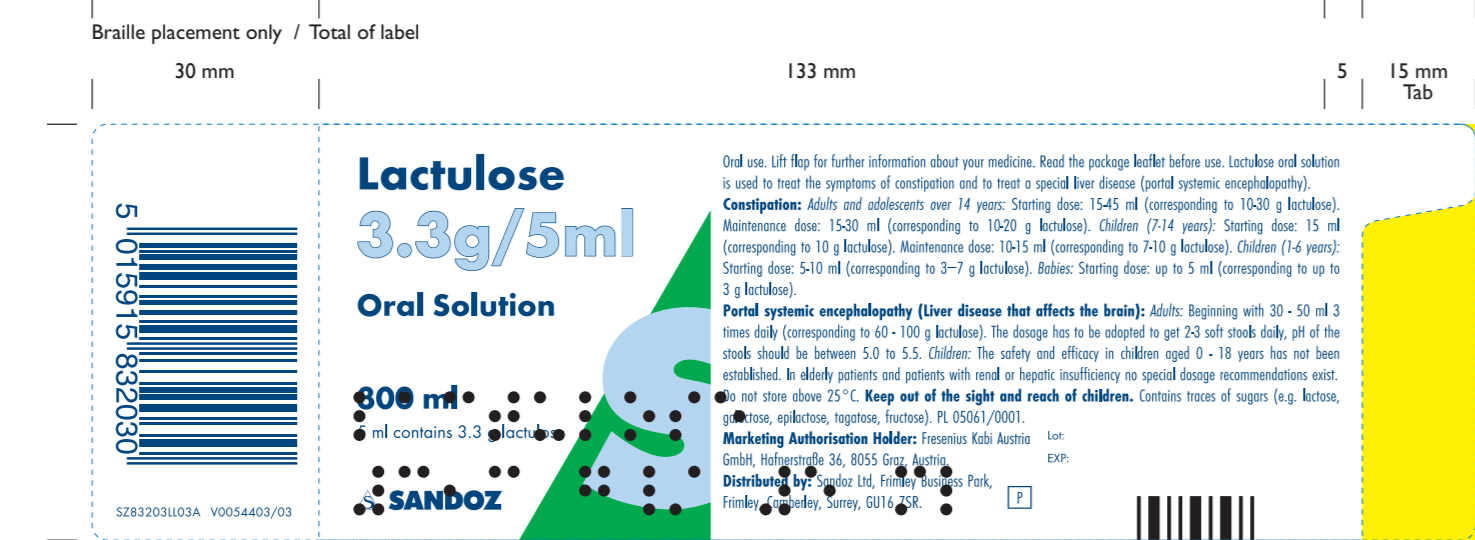
Lactulose 3.3g/5ml Oral Solution
300 ml
 5 ml contains 3.3 g lactulose
SANDOZ

For proofreading of Braille 30 mm 133 mm 5 15 mm Tab

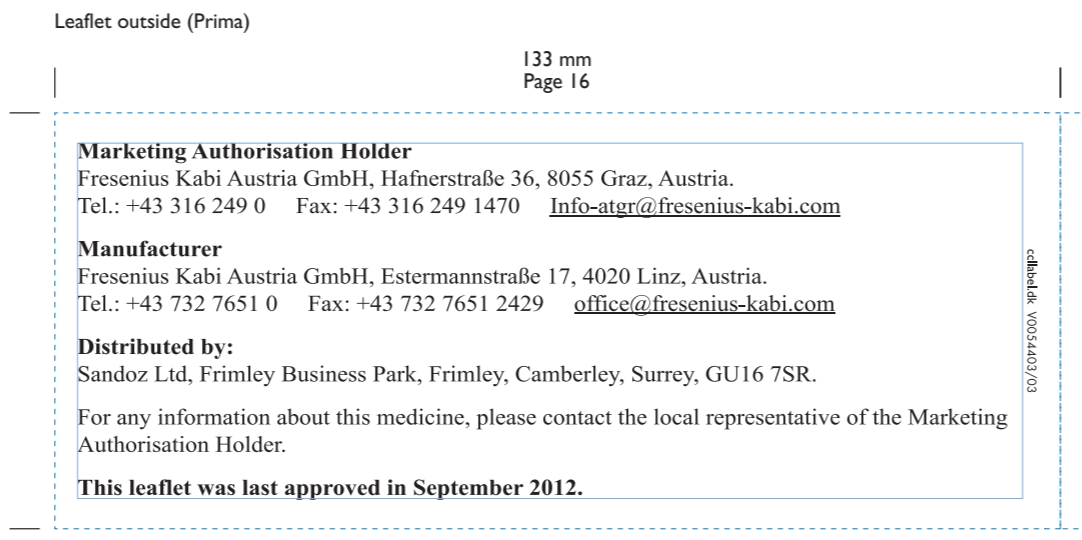


Braille placement only / Total of label

Braille placement only / Total of label 30 mm 133 mm 5 15 mm Tab

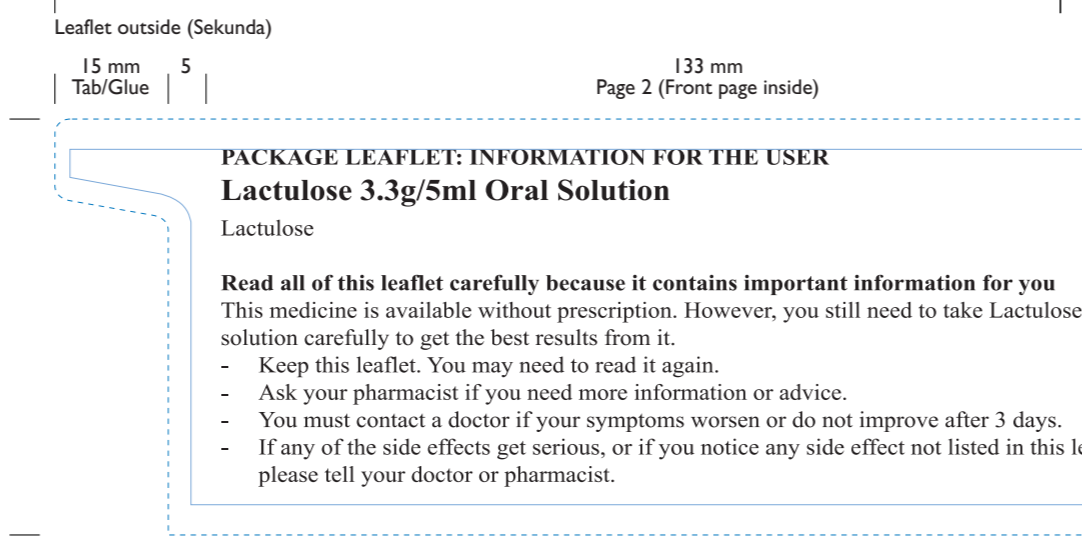


Leaflet outside (Prima) 133 mm Page 16 5 15 mm Tab



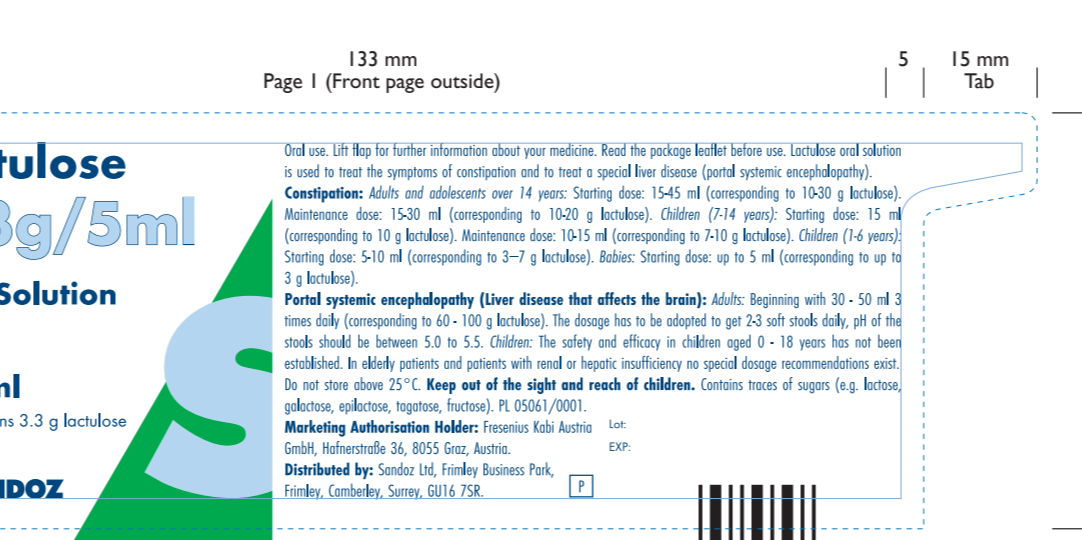
Marketing Authorisation Holder
 Fresenius Kabi Austria GmbH, Hafnerstraße 36, 8055 Graz, Austria.
 Tel.: +43 316 249 0 Fax: +43 316 249 1470 info-atm@fresenius-kabi.com
Manufacturer
 Fresenius Kabi Austria GmbH, Estermannstraße 17, 4020 Linz, Austria.
 Tel.: +43 732 7651 0 Fax: +43 732 7651 2429 office@fresenius-kabi.com
Distributed by:
 Sandoz Ltd, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR.
 For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.
This leaflet was last approved in September 2012.

Leaflet outside (Sekunda) 133 mm Page 2 (Front page inside) 5 15 mm Tab/Glue



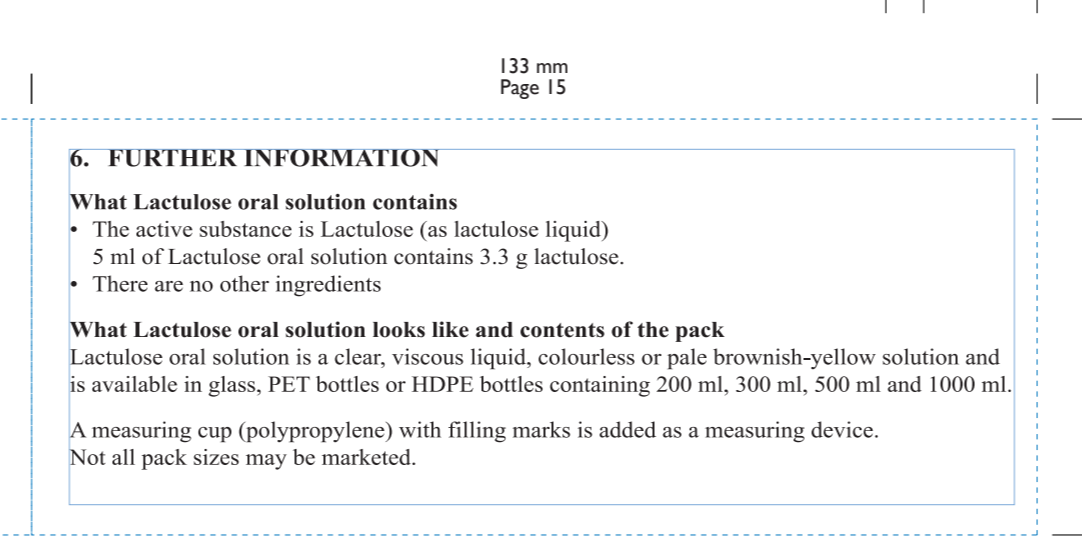
PACKAGE LEAFLET: INFORMATION FOR THE USER
Lactulose 3.3g/5ml Oral Solution
 Lactulose
Read all of this leaflet carefully because it contains important information for you
 This medicine is available without prescription. However, you still need to take Lactulose oral solution carefully to get the best results from it.
 - Keep this leaflet. You may need to read it again.
 - Ask your pharmacist if you need more information or advice.
 - You must contact a doctor if your symptoms worsen or do not improve after 3 days.
 - If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

133 mm Page 1 (Front page outside) 5 15 mm Tab



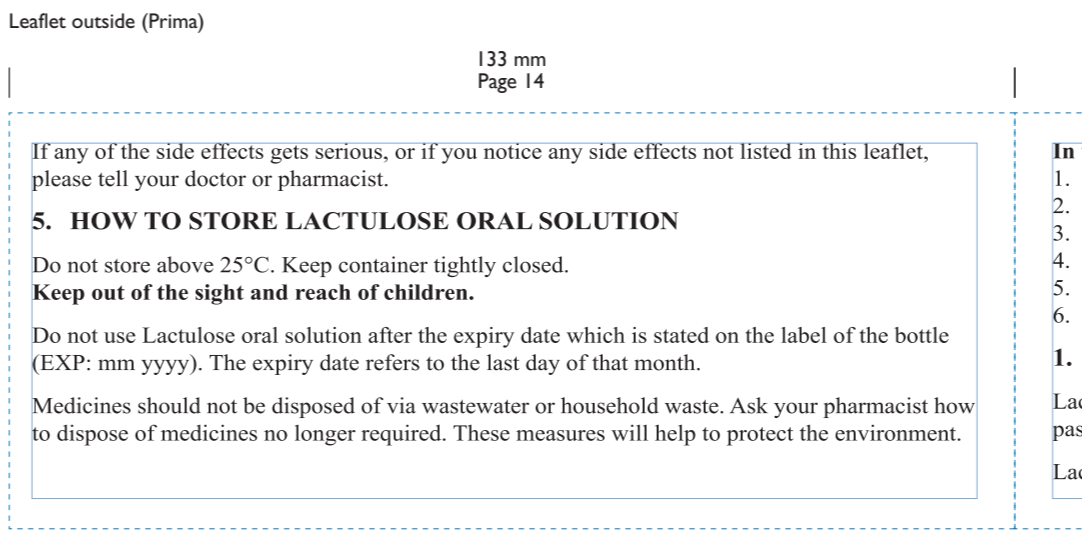
Lactulose 3.3g/5ml Oral Solution
300 ml
 5 ml contains 3.3 g lactulose
SANDOZ

133 mm Page 15 5 15 mm Tab



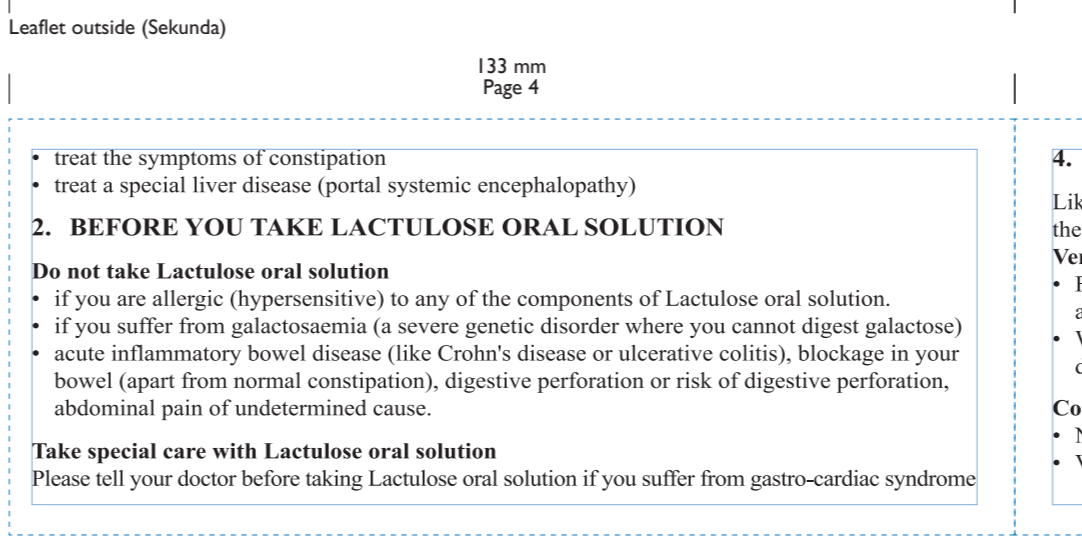
6. FURTHER INFORMATION
What Lactulose oral solution contains
 • The active substance is Lactulose (as lactulose liquid)
 • 5 ml of Lactulose oral solution contains 3.3 g lactulose.
 • There are no other ingredients.
What Lactulose oral solution looks like and contents of the pack
 Lactulose oral solution is a clear, viscous liquid, colourless or pale brownish-yellow solution and is available in glass, PET bottles or HDPE bottles containing 200 ml, 300 ml, 500 ml and 1000 ml.
 A measuring cup (polypropylene) with filling marks is added as a measuring device.
 Not all pack sizes may be marketed.

Leaflet outside (Prima) 133 mm Page 14 5 15 mm Tab



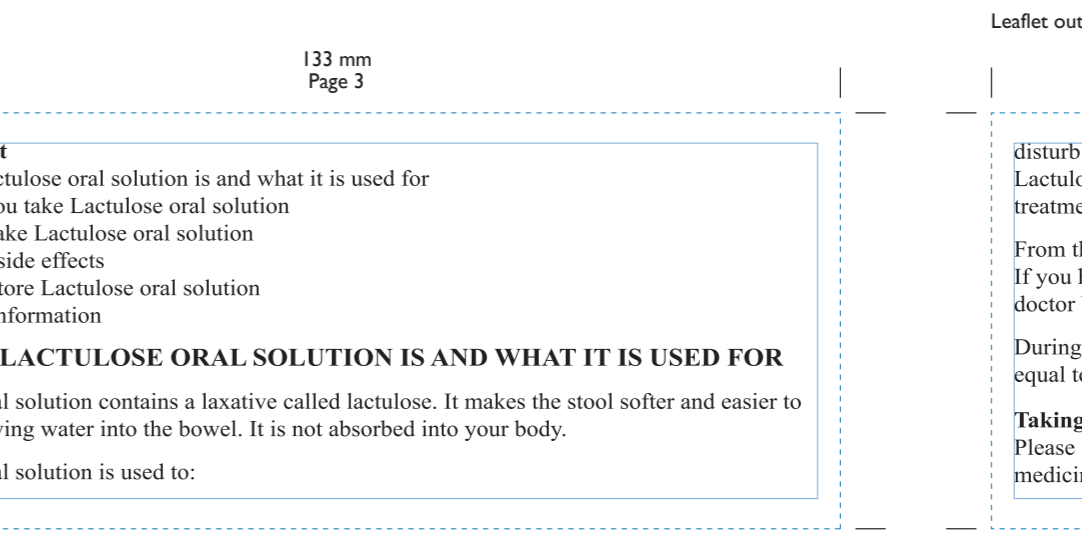
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
5. HOW TO STORE LACTULOSE ORAL SOLUTION
 Do not store above 25°C. Keep container tightly closed.
Keep out of the sight and reach of children.
 Do not use Lactulose oral solution after the expiry date which is stated on the label of the bottle (EXP: mm yyyy). The expiry date refers to the last day of that month.
 Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Leaflet outside (Sekunda) 133 mm Page 4 5 15 mm Tab



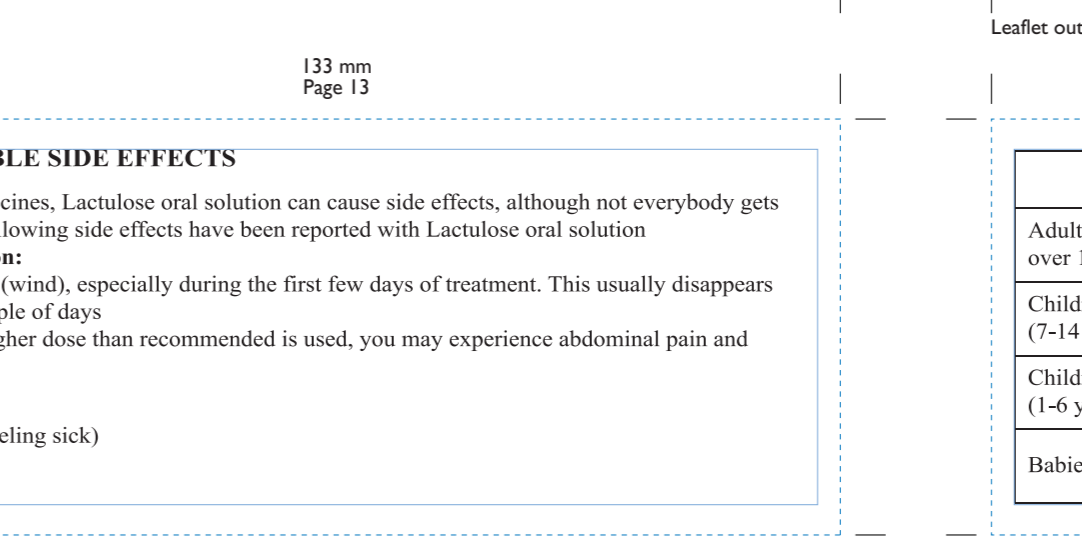
• treat the symptoms of constipation
 • treat a special liver disease (portal systemic encephalopathy)
2. BEFORE YOU TAKE LACTULOSE ORAL SOLUTION
Do not take Lactulose oral solution
 • if you are allergic (hypersensitive) to any of the components of Lactulose oral solution.
 • if you suffer from galactosaemia (a severe genetic disorder where you cannot digest galactose)
 • acute inflammatory bowel disease (like Crohn's disease or ulcerative colitis), blockage in your bowel (apart from normal constipation), digestive perforation or risk of digestive perforation, abdominal pain of undetermined cause.
Take special care with Lactulose oral solution
 Please tell your doctor before taking Lactulose oral solution if you suffer from gastro-cardiac syndrome

Leaflet outside (Prima) 133 mm Page 3 5 15 mm Tab



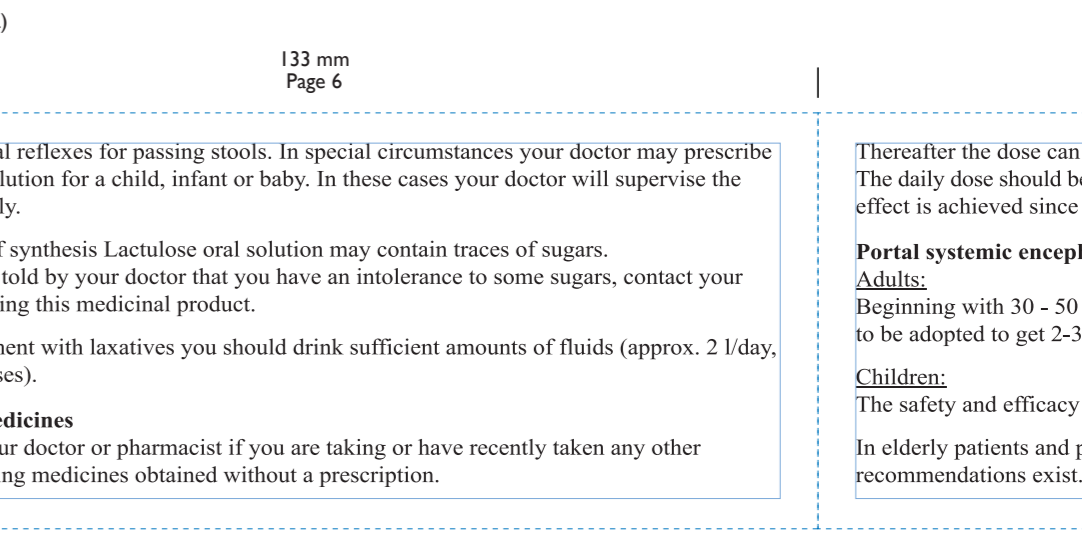
In this leaflet
 1. What Lactulose oral solution is and what it is used for
 2. Before you take Lactulose oral solution
 3. How to take Lactulose oral solution
 4. Possible side effects
 5. How to store Lactulose oral solution
 6. Further Information
1. WHAT LACTULOSE ORAL SOLUTION IS AND WHAT IT IS USED FOR
 Lactulose oral solution contains a laxative called lactulose. It makes the stool softer and easier to pass, by drawing water into the bowel. It is not absorbed into your body.
 Lactulose oral solution is used to:

Leaflet outside (Sekunda) 133 mm Page 13 5 15 mm Tab



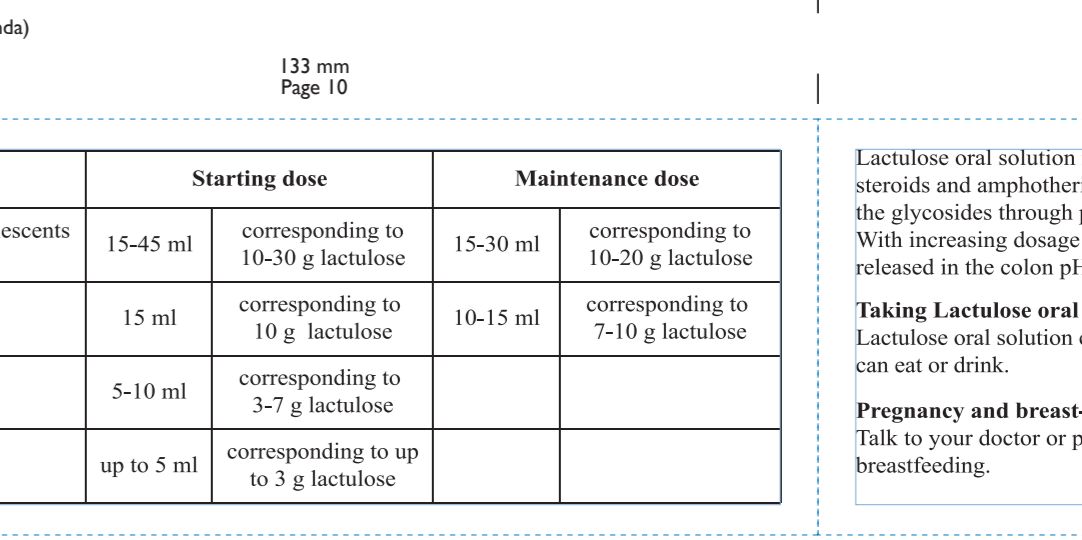
4. POSSIBLE SIDE EFFECTS
 Like all medicines, Lactulose oral solution can cause side effects, although not everybody gets them. The following side effects have been reported with Lactulose oral solution
Very common:
 • Flatulence (wind), especially during the first few days of treatment. This usually disappears after a couple of days
 • When a higher dose than recommended is used, you may experience abdominal pain and diarrhoea.
Common:
 • Nausea (feeling sick)
 • Vomiting

Leaflet outside (Prima) 133 mm Page 6 5 15 mm Tab



disturb the normal reflexes for passing stools. In special circumstances your doctor may prescribe Lactulose oral solution for a child, infant or baby. In these cases your doctor will supervise the treatment carefully.
 From the route of synthesis Lactulose oral solution may contain traces of sugars.
 If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
 During the treatment with laxatives you should drink sufficient amounts of fluids (approx. 2 l/day, equal to 6-8 glasses).
Taking other medicines
 Please inform your doctor or pharmacist if you are taking or have recently taken any other medicine, including medicines obtained without a prescription.

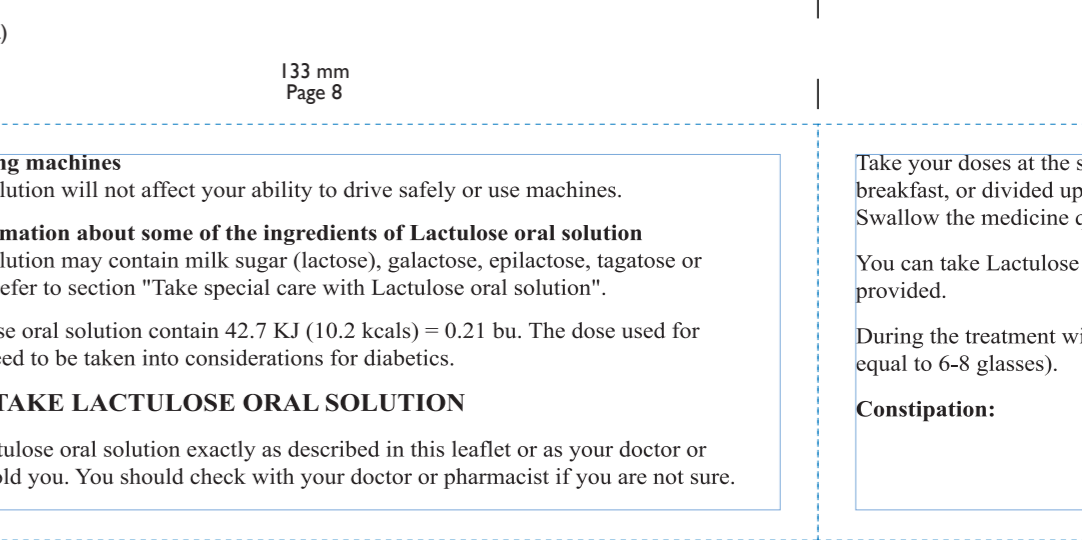
Leaflet outside (Sekunda) 133 mm Page 10 5 15 mm Tab



	Starting dose		Maintenance dose	
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		
Babies	up to 5 ml	corresponding to up to 3 g lactulose		

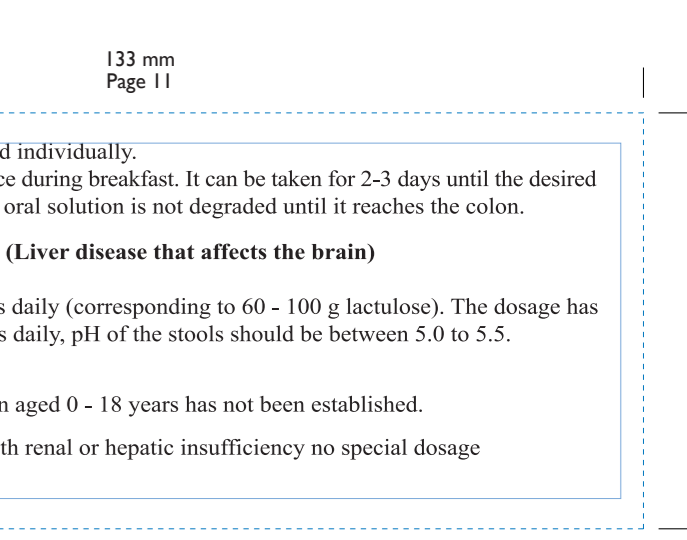
Lactulose oral solution may increase the loss of potassium induced by other drugs (e.g. thiazides, steroids and amphotericin B). Concomitant use of cardiac glycosides can increase the effect of the glycosides through potassium deficiency.
 With increasing dosage a decrease of pH-value in the colon is found. Therefore drugs which are released in the colon pH-dependently (e.g. 5-ASA) can be inactivated.
Taking Lactulose oral solution with food and drink
 Lactulose oral solution can be taken with or without food. There are no restrictions on what you can eat or drink.
Pregnancy and breast-feeding
 Talk to your doctor or pharmacist before you use Lactulose oral solution if you are pregnant or breastfeeding.

Leaflet outside (Prima) 133 mm Page 8 5 15 mm Tab



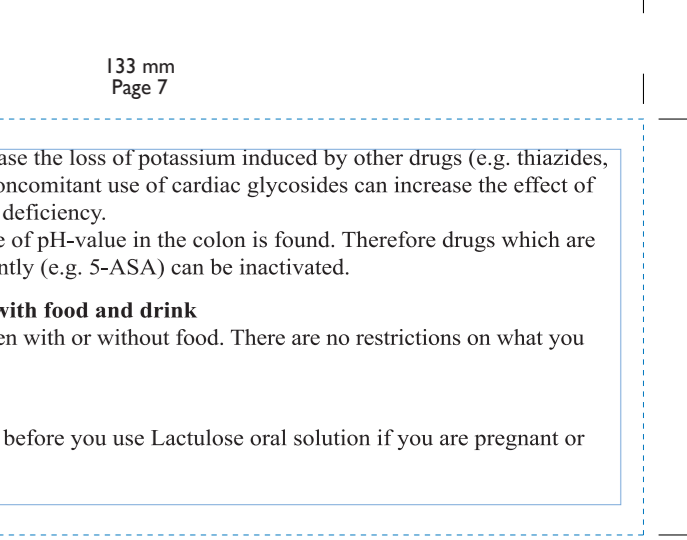
Driving and using machines
 Lactulose oral solution will not affect your ability to drive safely or use machines.
Important information about some of the ingredients of Lactulose oral solution
 Lactulose oral solution may contain milk sugar (lactose), galactose, epilactose, tagatose or fructose. Please refer to section "Take special care with Lactulose oral solution".
 15 ml of Lactulose oral solution contain 42.7 KJ (10.2 kcal) = 0.21 bu. The dose used for laxatives, because it hinders the individualisation of drug dose.
3. HOW TO TAKE LACTULOSE ORAL SOLUTION
 Always take Lactulose oral solution 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 not sure.

Leaflet outside (Prima) 133 mm Page 11 5 15 mm Tab



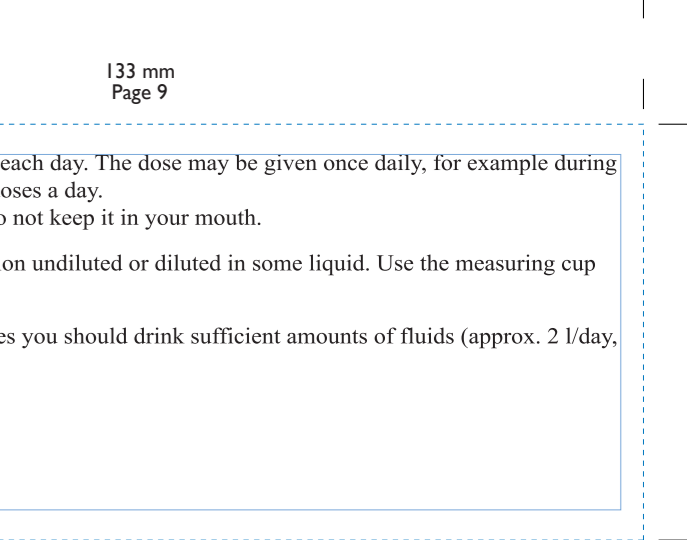
Thereafter the dose can be reduced individually.
 The daily dose should be taken once during breakfast. It can be taken for 2-3 days until the desired effect is achieved since Lactulose oral solution is not degraded until it reaches the colon.
Portal systemic encephalopathy (Liver disease that affects the brain)
Adults:
 Beginning with 30 - 50 ml 3 times daily (corresponding to 60 - 100 g lactulose). The dosage has to be adapted to get 2-3 soft stools daily, pH of the stools should be between 5.0 to 5.5.
Children:
 The safety and efficacy in children aged 0 - 18 years has not been established.
 In elderly patients and patients with renal or hepatic insufficiency no special dosage recommendations exist.

Leaflet outside (Sekunda) 133 mm Page 7 5 15 mm Tab



Lactulose oral solution may increase the loss of potassium induced by other drugs (e.g. thiazides, steroids and amphotericin B). Concomitant use of cardiac glycosides can increase the effect of the glycosides through potassium deficiency.
 With increasing dosage a decrease of pH-value in the colon is found. Therefore drugs which are released in the colon pH-dependently (e.g. 5-ASA) can be inactivated.
Taking Lactulose oral solution with food and drink
 Lactulose oral solution can be taken with or without food. There are no restrictions on what you can eat or drink.
Pregnancy and breast-feeding
 Talk to your doctor or pharmacist before you use Lactulose oral solution if you are pregnant or breastfeeding.

Leaflet outside (Prima) 133 mm Page 9 5 15 mm Tab



Take your doses at the same time each day. The dose may be given once daily, for example during breakfast, or divided up to three doses a day.
 Swallow the medicine quickly. Do not keep it in your mouth.
 You can take Lactulose oral solution undiluted or diluted in some liquid. Use the measuring cup provided.
 During the treatment with laxatives you should drink sufficient amounts of fluids (approx. 2 l/day, equal to 6-8 glasses).
Constipation: