PACKAGE LEAFLET: INFORMATION FOR THE USER

LACTECON, 3.335g/5 ml oral solution

Lactulose

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after several days

What is in this leaflet:

1. WHAT LACTECON IS AND WHAT IT IS USED FOR

What LACTECON is
LACTECON 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.

What LACTECON is used for
- LACTECON is used to treat constipation (infrequent bowel movements, hard and dry stools).

- LACTECON is used to treat hepatic encephalopathy, (a liver disease causing confusion, tremor, decreased level of consciousness including coma).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LACTECON

Do NOT take LACTECON
- if you are allergic (hypersensitive) to lactulose or any of the other ingredients of LACTECON (listed in section 6)
-if you suffer from
- galactosaemia (a severe genetic disorder where you cannot digest galactose)
- blockage in your gastrointestinal tract (apart from normal constipation)
- digestive perforation or risk of digestive perforation (damage/puncture to the gastric and/or intestinal wall)

If you are not sure, talk to your doctor or pharmacist before taking LACTECON.

Warnings and precautions
Talk to your doctor or pharmacist before taking LACTECON if you suffer from any medical conditions or illnesses, in particular:
- if you suffer from unexplained tummy ache
- if you are unable to digest milk sugar (lactose)
- if you have diabetes.

You should not take LACTECON if you suffer from:
- galactose or fructose intolerance

- Lapp lactase deficiency
- glucose-galactose malabsorption

The usual dose of LACTECON in constipation is unlikely to affect diabetics. If you have diabetes and are treated for hepatic encephalopathy, your dose of LACTECON will be higher. This high dose contains a large amount of sugar. Therefore, you may need to adjust the dose of your anti-diabetic medicine.

LACTECON can influence the normal reflexes for passing stools.

Chronic use of unadjusted dosages (exceeding 2-3 soft stools per day) or misuse can lead to diarrhoea and disturbance of the electrolytes balance. If you are prone to develop electrolyte disorders (e.g. patients with renal or hepatic impairment, patients receiving concomitant diuretics) talk to your doctor or pharmacist before taking LACTECON.

During the treatment with laxatives you should drink sufficient amounts of fluids.
If you take LACTECON for several days and there is no improvement in your condition or if your symptoms worsen, please contact your doctor. Please do not use LACTECON without medical advice longer.

Other medicines and LACTECON
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

LACTECON with food and drink
LACTECON can be taken with or without food. There are no restrictions on what you can eat or drink.

Pregnancy, breast-feeding and fertility
LACTECON can be used during pregnancy and breast-feeding. No effects on fertility are to be expected. Ask your doctor or pharmacist for advice before taking any medicine.

Children
In special circumstances, your doctor may prescribe LACTECON for a child, infant or baby. In these cases, your doctor will supervise the treatment carefully.

Driving and using machines
LACTECON has no or negligible influence on your ability to drive safely or use machines.

Important information about some of the ingredients of LACTECON
LACTECON may contain sugars, e.g. milk sugar (lactose), galactose, or fructose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE LACTECON

Always take LACTECON exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Take your doses at the same time each day.
Swallow the medicine quickly. Do not keep it in your mouth.

You can take LACTECON oral solution undiluted or diluted in some liquid. You may use the measuring cup provided.

<u>Dosing in constipation</u>
The dose may be given once daily, for example during breakfast, or divided into two doses a day, by using the measuring cup.

After a few days, the starting dosage may be adjusted to the maintenance dose based upon your treatment response. Several days (2-3 days) of treatment may be needed before treatment effect occurs.

Patient	Starting dose daily	Maintenance dose daily
Adults and adolescents (≥15 years)	15-45 ml	15 - 30 ml
Children (7-14 years)	15 ml	10 - 15 ml
Children (1-6 years)	5-10 ml	5-10 ml
Infants under 1 year	2.5 -5 ml	up to-5 ml

Use in Children
Use of laxatives in children, infants, and babies should be exceptional and under medical supervision. Please do not give LACTECON to children (<14 years) before consulting your doctor for prescription and careful supervision.

Dosing in hepatic encephalopathy (for adults only)
The starting dose for hepatic encephalopathy is 30 to 45 ml oral solution given 3 to 4 times a day. This dose may be adjusted to the maintenance dose to achieve 2-3 soft stools per day.

Use in Children
No data are available for treatment of children (newborn to 18 years of age) with hepatic encephalopathy.

Use in elderly patients
No special dosage recommendations exist.

Use in patients with renal or hepatic insufficiency
No special dosage recommendations exist.

If you take more LACTECON than you should
In case of overdose, you may experience diarrhoea, a loss of electrolytes, and abdominal pain. Contact your doctor or pharmacist if you have taken more LACTECON than you should.

If you forget to take LACTECON
If you forget to take a dose of LACTECON, do not worry. Just take the next dose at the usual time.
Do not take a double dose to make up for a forgotten dose.

If you stop taking LACTECON
Do not stop or change the treatment before talking to your doctor.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, LACTECON can cause side effects, although not everybody gets them.

The following side effects have been reported with LACTECON:

Very common (may affect more than 1 in 10 people)
Diarrhoea

Common (may affect up to 1 in 10 people)
Flatulence (wind)
Nausea (feeling sick)

Vomiting
Abdominal pain

Uncommon (may affect up to 1 in 100 people)
Electrolyte imbalance due to diarrhoea

Flatulence may occur during the first few days of treatment. As a rule, it disappears after a few days. When dosages higher than instructed are used, abdominal pain and diarrhoea may occur. In such a case, the dosage should be decreased.

If you use high doses (normally only associated with hepatic encephalopathy, HE) for an extended period of time, the patient may experience an electrolyte imbalance due to diarrhoea.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE LACTECON

- Keep this medicine out of the sight and reach of children.
- Do not store LACTECON above 25° C. Do not refrigerate.
- Do not use LACTECON after the expiry date, which is stated on the carton or bottle. 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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What LACTECON contains
The active substance in LACTECON is lactulose.
One ml of LACTECON oral solution contains 667 mg lactulose. Five ml of LACTECON oral solution contain 3.335 g lactulose.
LACTECON does not contain any ingredients. However, it may contain sugars, such as lactose, galactose, and fructose from the route of synthesis.

Lactecon may contain sulfite from the route of synthesis.

What LACTECON looks like and contents of the pack
LACTECON oral solution is a clear, viscous liquid, colourless to brownish yellow.

LACTECON oral solution is available in 200 ml, 300 ml, 500 ml or 1000 ml plastic bottles with a plastic measuring cup. The graduations on the measuring cup are: 2.5 ml, 5 ml, 10 ml, 15 ml, 20 ml, 25 ml, and 30 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13.

Manufacturer:
Abbott Biologicals BV
Veerweg 12

8121 AA Olst
Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

France	Lactulose Biphar
Ireland	Lactecon
Slovakia	Lactecon
Slovenia	Lactecon

This leaflet was last approved in November 2018