

Patient Information Leaflet

Gutclear® Syrup PI

(Lactitol Monohydrate Syrup 66.67% w/v)

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, pharmacist or nurse has 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

1. What Gutclear® Syrup is and what it is used for
2. What you need to know before you take Gutclear® Syrup ® Syrup
3. How to take Gutclear® Syrup
4. Possible side effects
5. How to store Gutclear® Syrup
6. Contents of the pack and other information

1. WHAT Gutclear® Syrup IS AND WHAT IT IS USED FOR

The name of this medicine is Gutclear® Syrup, which contains lactitol. It is a laxative for the treatment of chronic constipation and prevention of hepatic encephalopathy in adults, adolescents and elderly. Lactitol exerts an osmotic effect, causing the influx of water into the small intestine leading to a laxative effect in the colon.

Lactitol promotes retention of water within the bowel lumen, softening the stool and increasing the bowel volume. Hydration of the gut content and reduction in intra-luminal pH also results in shorter transit time and the establishment of laxation.

Lactitol decreases blood ammonia concentration by inhibiting both the production and the absorption of ammonia by reducing intestinal pH and shortening the residence time of intestinal contents in the intestinal tract and hence improves hepatic encephalopathy.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE Gutclear® Syrup

Do not take **Gutclear® Syrup** if your doctor has told you that you have:

- Patients with the undiagnosed abdominal pain, colic, bleeding or vomiting.
- Patients with intestinal obstruction, ileostomy, colostomy, appendicitis or diverticulitis.
- Patients with galactosemia (disease which impairs the body's ability to process and produce energy from a sugar called galactose)
- Patients hypersensitive to the drug or any other component of the formulation.

Warnings and Precautions

- It is suggested that individuals taking Gutclear® Syrup have their fluid and salt (electrolyte) balance monitored regularly especially in elderly patients on long term treatment.
- Treatment with Gutclear® Syrup may cause accumulation of hydrogen in the bowel; patient should be advised to have a thorough bowel cleansing with a non-fermentable solution.

Other medicines and Gutclear® Syrup

Gutclear® Syrup should not be administered with other laxatives. Caution may be exercised in using Gutclear® Syrup with drugs causing potassium loss like loop diuretics. Gutclear® Syrup can increase digitalis toxicity. Reduction in acidification effect can be observed if broad spectrum antibacterial agents or antacids are administered along with Gutclear® Syrup.

Pregnancy

Gutclear® Syrup should be prescribed only if the potential benefits outweigh the risks to the fetus.

Lactation

No studies are available on the secretion of Gutclear® Syrup in breast milk. There are no data on the presence of lactitol in human or animal milk, the effects on the breastfed infant, or the effects on milk production.

Driving and using machines

Gutclear® Syrup does not affect your ability to drive or use machines.

3. HOW TO TAKE GUTCLEAR® SYRUP

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

Taking this medicine

- Take Gutclear® Syrup from measuring cup.
- You can mix it with fruit juice or water. It is recommended that you drink plenty of fluids (approximately 6-8 glasses throughout the day).
- Swallow the dose immediately. Do not keep it in your mouth as the sugar content may lead to tooth decay, particularly if the syrup is taken for long periods.
- The syrup takes 2 to 3 days to start working.
- After this time, you may be able to reduce the dose you take according to your needs.

Constipation

Adults and adolescents: The starting dose is 30 ml. After this the dose can be adjusted to 15-30ml.

Use in Children: Use of laxatives in children, infants, and babies should be exceptional and under medical supervision because it can influence the normal reflexes for passing stools. Please do not give the syrup to children (under 14 years) before consulting your doctor for prescription and careful supervision.

Gutclear® Syrup is given as a single dose with the morning or evening meal, subsequently adjusted to produce one stool daily.

Hepatic encephalopathy

Adults: The usual starting dose 30-45 ml in 3 to 4 times a day.

Use in Children: No information is available for treatment of children (new-born to 18 years of age) with hepatic encephalopathy.

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

The dose is subsequently adjusted to produce 2 soft stools daily. Doses should be mixed with food or liquid, and it is recommended to drink 1 to 2 glasses of liquid with the meal.

If you take more Gutclear® Syrup than you should

You may develop excessive diarrhoea, which can lead to dehydration. If this occurs, stop taking Gutclear® Syrup and drink plenty of fluids. If you are worried contact your doctor or pharmacist.

If you forget to take Gutclear® Syrup

Take the dose as soon as you remember to take it.

4. POSSIBLE SIDE EFFECTS

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

The most commonly observed adverse effects with Gutclear® Syrup are abdominal cramps, distension or flatulence during the first 10 days of treatment which may likely to disappear after continued administration. The other less frequent side effects in abdominal pain, loose motions, nausea and vomiting, anal itching.

Tell your doctor immediately and stop taking Gutclear® Syrup if you:

Get a serious allergic reaction which causes difficulty in breathing, or swelling of the face, lips, tongue or throat.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top of the home page.

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

You can also report the side effect with the help of your treating physician.

5. HOW TO STORE GUTCLEAR® SYRUP

Keep this medicine out of the sight and reach of children.

Do not use Gutclear® Syrup after the expiry date which is stated on the carton. Store below 30°C. Protect from light. Do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Gutclear® Syrup contains

Each 15 ml contains Lactitol Monohydrate 10 g and Benzoic Acid is 0.0225 g

Gutclear® Syrup is available in 100 or 200ml bottles.

Marketing Authorisation Holder

Zuventus Healthcare Ltd.

Zuventus House, Plot Y2, CTS No: 358/A2,

Near Nahur Railway Station,

Nahur (West), Mumbai 400 078

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