Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Gutclear Syrup

2. Qualitative and quantitative composition

Each 15 ml syrup contains:
Lactitol Monohydrate USP..... 10 g
Benzoic Acid USP..... 0.0225 g

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Colourless syrup

4. Clinical particulars

4.1 Therapeutic indications

Gutclear is indicated for treatment of constipation and prevention of hepatic encephalopathy.

4.2 Posology and method of administration

Posology

In the treatment of constipation, the recommended dose of Gutclear is as follows
Adults: 15-30 ml/day (10-20 g/day)
Pediatrics: 250-400 mg/kg/day
Gutclear is given as a single dose with the morning or evening meal, subsequently adjusted to produce one stool daily.
In the treatment of hepatic encephalopathy, Gutclear is given in usual oral doses of 500 to 700 mg/kg daily in 3 divided doses at meal times. 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.

4.3 Contraindications

Patients with the undiagnosed abdominal pain, colic, bleeding or vomiting
Patients with intestinal obstruction, ileostomy, colostomy, appendicitis or diverticulitis
Patients with galactosemia
Patients hypersensitive to the drug or any other component of the formulation

4.4 Special warnings and precautions for use

It is suggested that individuals taking Gutclear have their fluid and salt (electrolyte) balance monitored regularly especially in elderly patients on long term treatment.

Treatment with Gutclear may cause accumulation of hydrogen in the bowel; patient should be advised to have a thorough bowel cleansing with a non-fermentable solution.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Pregnancy and Lactation

Pregnancy

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

Lactation

No studies are available on the secretion of lactitol in breast milk.

4.7 Effects on ability to drive and use machines

Lactitol has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The most commonly observed adverse effects with Gutclear are abdominal cramps, distension or flatulence during the first 10 days of treatment which are likely to disappear after continued administration. The other less frequent side effects are abdominal pain, diarrhoea, nausea and vomiting, anal pruritus, borborygmii or steatorrhea.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

No data on overdosage of Lactitol is available. If a patient consumes large amount of Lactitol, symptoms of abdominal pain and diarrhea may appear. There may also be electrolyte imbalance. There is no specific antidote known for Lactitol over dosage. Gastric lavage may be instituted at the earliest to remove the remnant drug from the stomach. Patient should be treated symptomatically and electrolyte levels should be monitored periodically.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of action

Once ingested, Lactitol is neither hydrolysed nor absorbed in the small intestine. It is passed undigested to the colon and a substantial proportion of orally ingested lactitol becomes substrate for the resident colonic microflora where it is slowly fermented and is converted into short-chain fatty acids (SCFAs). The liberation of short-chain fatty acids causes a fall in pH of the right colon. The fall in pH results in the formation of an acidic media. The reduction in intra-luminal pH increases the intra-luminal osmolality. This 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. Lactitol also favors the growth of saccharolytic (healthy) bacteria in the gut.

5.2 Pharmacokinetic properties

Lactitol is poorly absorbed from the gastrointestinal tract in healthy volunteers and patients with cirrhosis, and it does not disturb glucose or lactate homeostasis. Following oral administration of Lactitol 0.5 g/kg, no Lactitol is found in serum and is metabolised. short chain fatty acids in the large intestine. The urinary excretion of Lactitol over 24 h ranged from 0.1 to 1.4% of the administered dose (0.46% in cirrhotics and 0.35% in healthy volunteers). Blood D- and L-lactate and plasma glucose did not increase following Lactitol.

5.3 Preclinical safety data

The single dose toxicity studies of lactitol, a hepatic encephalopathy drug, were performed in ddY mice and SD rats of both sexes by administering the drug orally, intravenously or subcutaneously. The drug was administered as a single dose followed by a 14-day observation. Oral LD50 values of lactitol were estimated to be between 23 and 30 g/kg in male mice, approximately 30 g/kg in female mice, and more than 30 g/kg in male and female rats. Lethal dose was more than 10 g/kg intravenously and subcutaneously in mice and rats of both sexes. The signs of toxicity in mice and rats observed following the administration of this drug included the following: decreased spontaneous movement [p.o., i.v., s.c.]; diarrhea, oligopnea or prone position, transient decreased body weight [p.o]. There were no treatment-related changes in gross examination. Based on these results, it was found that lactitol had a very low acutetoxicity when administered by a single dose method in mice and rats.

6 Pharmaceutical Particulars

6.1 List of Excipients

Benzoic acid and purified water

6.2 Incompatibilities

Gutclear may reduce the absorption of concomitantly administered oral medications. Administer oral medications at least 2 hours before or 2 hours after Gutclear

6.3 Shelf-Life
36 MONTHS

6.4 Special Precautions for storage
Store below 30 °C. Protect from light. Do not freeze

6.5 Nature and Content of container
100 ml or 200 ml syrup filled in amber colour PET bottle with a silver PP cap with EP wad and 15 ml measuring cup. One such pack is placed along with a leaflet in a carton.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 Marketing Authorization Holder
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10 Date of revision of the text
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