

ColonLYTELY

PEG 3350 & ELECTROLYTES Powder For Oral Solution

Consumer Medicine Information

Composition

Polyethylene Glycol 59 g Sodium Sulfate (anhyd) BP 5.68 g Sodium Bicarbonate BP 1.69 g Sodium Chloride BP 1.46 g Potassium Chloride BP 0.75 g combined into a readily soluble powder.

ColonLYTELY LEMON also contains Acesulfame potassium, Lemon flavour Trusil and Calcium cyclamate.

Action

Orally administered ColonLYTELY induces a bowel evacuation which rapidly cleanses the bowel, usually within four hours.

The osmotic activity of polyethylene glycol 3350 and the electrolyte concentration result in virtually no net absorption or secretion of ions. Accordingly, large volumes may be administered without significant changes in fluid or electrolyte balance.

Indications and Usage:

Cleansing of the lower bowel in preparation for endoscopic, radiological or surgical gastrointestinal examination.

Contra-indications:

ColonLYTELY is contraindicated in patients with gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or toxic megacolon. All laxatives are contraindicated in patients with cramps, colic, nausea, vomiting or any undiagnosed abdominal pain.

Warnings:

No additional ingredients (eg. flavourings) should be added to the solution unless especially permitted by the physician.

ColonLYTELY should be used with caution in patients with severe ulcerative colitis.

Precautions

Patients with impaired gag reflex or in an unconscious state, or semiconscious patients and patients prone to regurgitation or aspiration should be observed during administration of ColonLYTELY especially if it is given via nasogastric tube.

Preparation of Solution:

ColonLYTELY solution is prepared by dissolving the contents of one sachet in one litre of water or, if specifically permitted by the physician, cordial or clear fruit juice. This process is repeated until the required volume is prepared.

Information for Patients:

ColonLYTELY produces a watery bowel evacuation which cleanses the bowel, usually prior to a bowel examination.

For best results no solid food should be consumed during the 3 to 4 hour period before drinking the solution, but in no case should solid foods be eaten within 2 hours of taking ColonLYTELY.

Prepare the solution according to the instructions on the sachet. The solution is more palatable if chilled to taste. Gradually drink a cupful (about 250 mL) every 10 minutes. The first bowel movement should occur approximately one hour after the start of ColonLYTELY administration.

You may experience some abdominal bloating and distension before the bowels start to move. If severe discomfort or distention occur, stop drinking for a while, or drink each portion at longer intervals until these symptoms disappear.

Continue drinking until the watery motions are clear and free of solid matter. This usually requires at least 3 litres, and it is best to drink all of the solution. Any unused remaining portion should be discarded.

Are you on any other medication?

Speak to your doctor about when to take any other medication you may be taking.

General Laxative Warnings

Do not use a laxative product when nausea, vomiting, or abdominal pain is present, unless directed by a physician.

If you have noticed a sudden change in bowel habits that persists over a period of two weeks, consult a physician before using a laxative.

Rectal bleeding or failure to have a bowel movement may indicate a serious condition. Discontinue use and consult a physician.

Laxative products should not be used longer than one week unless directed by a physician.

Frequent or prolonged use of a laxative may result in dependence on laxatives.

Keep this and all drugs out of the reach of children.

In case of accidental overdose or ingestion seek professional assistance or contact a Poison Control Centre immediately.

Drug Interactions:

Oral medication administered within one hour of the start of administration of ColonLYTELY may be flushed from the gastrointestinal tract and not absorbed.

Use in Pregnancy:

Category C. Animal reproduction studies have not been conducted with ColonLYTELY. ColonLYTELY should only be administered during pregnancy if clearly needed.

Australian categorisation definition of Category C:

Drugs which, owing to their pharmacological effects have caused or may be suspected of causing, harmful effects on the human foetus or neonate without causing malformations.

These effects may be reversible.

Paediatric Use:

Safety in children has not been established.

Use in children must be solely at a physician's discretion.

Adverse Reactions

Adverse effects are transient and subside rapidly. ColonLYTELY administration is associated with a low incidence of side effects, primarily nausea, abdominal fullness and bloating.

Abdominal cramps, vomiting, and anal irritation occur less frequently. Isolated cases of urticaria, rhinorrhoea and dermatitis have been reported and may represent allergic reactions.

DOSAGE and ADMINISTRATION

Endoscopy or Colonoscopy :

The recommended dosage for adults is three to four litres of ColonLYTELY solution prior to endoscopic, radiological or surgical gastrointestinal examination.

Ideally the patient should fast for approximately three to four hours prior to ColonLYTELY administration.

In no case should solid food be given for at least two hours before the solution is given.

ColonLYTELY is usually taken orally but may be given via nasogastric tube to patients who are unwilling or unable to drink the preparation.

Oral administration is at the rate of 250ml every ten minutes until three to four litres is consumed or rectal effluent is clear.

Nasogastric tube administration is at the rate of 20 to 30ml per minute (approximately 1.5 litres per hour). The first bowel movement should occur approximately one hour after the start of ColonLYTELY administration. Various regimens have been used. One method is to schedule patients in midmorning or later allowing the patients three hours for drinking and an additional hour for complete bowel evacuation.

Another method is to administer ColonLYTELY on the evening before the examination particularly if the patient is to have a barium enema.

Barium enema:

To ensure that too much fluid does not remain in the bowel the administration of two litres of ColonLYTELY together with two tablets of bisacodyl 5mg on the night prior to the procedure results in bowel clearance at least equal to that obtainable by rectal wash-outs and avoids undue discomfort to the patient and reduces preparation time by nursing staff.

Laxative:

In cases of long-standing or problem constipation as a safe, acceptable alternative to enemas, suppositories, irritant laxatives or digital extraction. A dose of two litres of ColonLYTELY is recommended to be consumed over a two hour period. May be dissolved in cordial to improve palatability. Bowel movements should start within about 1 hour after the start of ColonLYTELY administration.

Pack

ColonLYTELY ORIGINAL: In powdered form as a 68.58g powder sachet, that is coloured BLUE, containing sufficient to produce a ONE litre preparation when dissolved in water. and

ColonLYTELY LEMON: In powdered form as a 70g powder sachet, that is coloured GREEN, containing sufficient to produce a ONE litre preparation when dissolved in water.

Storage:

To be stored in a dry place at less than 30°C

Shelf life is 2 years from date of manufacture.

When reconstituted, keep solution refrigerated.

Discard unused reconstituted solution within 72 hours.

Poison Schedules:

No restriction Any State and A.C.T.

ARTG Registration Number:

ColonLYTELY ORIGINAL: AUST R 30138

ColonLYTELY LEMON: AUST R 29995

SPONSOR:

Dendy Pharmaceuticals Ltd, 45 COMER

STREET

EAST BRIGHTON VIC 3187

ACN 007 180 985

Tel: (03) 9593 005

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