

ColonLYTELY[®]

ColonLYTELY PEG¹ 3350 (Macrogol) and balanced electrolytes for oral solution 'Macrogol 3350 with sodium sulfate and electrolytes oral liquid (powder for)'²

About ColonLYTELY

ColonLYTELY is an osmotic colonoscopy preparation that is used to cleanse the lower bowel in preparation for medical procedures such as:

- Colonoscopy
- Bowel evacuation
- Endoscopy
- Abdominal X-ray examination
- Abdominal surgery

However, your doctor may prescribe ColonLYTELY for another purpose.

Before you take ColonLYTELY

Do not take ColonLYTELY if your doctor has told you that you have:

- An obstruction in your intestine (gut)
- A perforated gut wall
- Gastric retention
- Severe inflammatory bowel disease, like ulcerative colitis, Crohn's disease, or toxic megacolon
- An allergy to macrogol or other ingredients in the product.

If you are pregnant or breastfeeding, talk to your doctor before you take ColonLYTELY.

If you are taking other oral medicines, speak to your doctor. Most other oral medicines should be taken at least one hour before or one hour after taking ColonLYTELY because they may be flushed through your digestive system and not work so well. However, some medicines such as sustained release preparations or medicines with a narrow therapeutic window, such as the contraceptive mini-pill, may need to be taken more than one hour before or after ColonLYTELY.

Contraceptive cover from the oral contraceptive pill is likely to be incomplete if it is taken at any time during the process of bowel cleansing with ColonLYTELY (an hour before the first dose of ColonLYTELY until after the investigation). Therefore, an alternative method of contraception should be used for the length of the cycle when ColonLYTELY is taken.

Patients with diabetes should consult their doctor prior to use of ColonLYTELY.

When to take ColonLYTELY

Carefully follow all directions given to you by your doctor. They may differ from the information contained in this page.

Important: Do not take any solid food from when you start to take ColonLYTELY until after the examination.

Two days before your procedure

Avoid eating brown bread, red meat, cereals, yellow cheese, vegetables, fruit or anything with nuts or seeds in it.

One day before your procedure

Only drink approved clear liquids

Clear liquids include: water, clear soup, tea or coffee (without milk or non-dairy creamer), all of the following liquids which are not coloured red or purple: fruit juices without pulp, carbonated or non-carbonated soft drinks, fruit-flavoured cordials.

Approved clear liquids include:

- Water
- Clear fruit juice – apple juice (no pulp)
- Clear cordials (not red or purple)
- Soft drinks
- Jelly (yellow or orange)
- Sports drinks or Gastrolyte
- Black tea or coffee sweetened to taste (no milk, soy or whiteners)
- Clear soups, chicken or beef broth
- Barley sugar is allowed

Note:

- You should not drink anything coloured red or purple.
- Do not drink water alone.
 - Drinking only water to replace the fluid losses may lead to electrolyte imbalance, particularly hyponatraemia (low sodium), and possibly seizures.
- A combination of these approved clear liquids will give a variety of fluid intake.

When taking ColonLYTELY, it is important to maintain hydration and electrolyte balance.

How to prepare ColonLYTELY

Add the contents of one sachet into a one litre container. Pour one litre of water into the container and stir until all the powder has dissolved and the ColonLYTELY solution is clear or slightly hazy. This may take up to 5 minutes.

How to drink ColonLYTELY

- Try to drink a glassful every 10 to 15 minutes.
- Drink a litre of the ColonLYTELY solution, taking your time.
- During the course of this treatment, drink a further one litre of clear liquid to prevent you from feeling very thirsty and becoming dehydrated.
- Please refer to the section titled 'When to take ColonLYTELY'

What to expect when taking ColonLYTELY

ColonLYTELY will induce frequent, loose bowel movements.

The onset of action will vary from person to person.

You should:

- Remain within easy reach of toilet facilities at all times while using ColonLYTELY
- Not plan any other activities until after your procedure or examination
- Consider using a plastic cover sheet as a mattress protector for the bed
- Arrange for someone to take you to and from the procedure or medical examination
- Replenish your system by drinking liquids after returning home from your procedure.

How to reduce discomfort

During the period of taking ColonLYTELY, you should consider the following:

- Loose-fitting clothing is recommended
- Alcohol-free and fragrance-free wet wipes and soft toilet tissue may minimise the expected irritation from wiping
- Frequent application of a protective cream, lanolin, petroleum jelly (Vaseline) or zinc cream will reduce discomfort.

Side effects of ColonLYTELY

Like all medicines, ColonLYTELY can have side effects.

You may feel full in the stomach, nauseous, have stomach pains or soreness around the anus.

If you experience fullness, nausea or stomach pains, take ColonLYTELY more slowly until these feelings stop. If the feelings do not stop, consult your pharmacist or doctor.

There is a possibility of vomiting.

If you have other unpleasant side effects, tell your doctor or pharmacist.

Blood sodium levels could also decrease, particularly if you take medicines that affect your kidneys, such as ACE inhibitors and diuretics used for the treatment of heart disease. Very low blood sodium levels can cause convulsions (fits).

If your blood sodium levels change, you may feel breathless, very thirsty with a severe headache or get puffy ankles.

There have been rare reports of severe allergic reactions to Macrogol 3350 (an ingredient in ColonLYTELY). Signs of severe, life-threatening allergic reaction include sudden signs of allergy, such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

If you experience any of these reactions, stop taking ColonLYTELY and tell your doctor immediately, or go to the Accident and Emergency department at your nearest hospital.

How to store ColonLYTELY

Keep ColonLYTELY sachets at room temperature (below 30°C), stored in their original packaging, and do not use after the expiry date on the label.

After you have dissolved ColonLYTELY in the water, the solution may be stored (kept covered) at room temperature (below 30°C), or put it in the fridge (2–8°C). Do not freeze the solution and do not keep it for more than 24 hours.

Keep all medicines away from children.

Product description – ingredients

ColonLYTELY is available in two flavours: Original and Lemon, in convenient powder sachets for reconstitution to 1 litre:

ColonLYTELY Original 68.58g sachets
Macrogol with Electrolytes
Each sachet prepares a 1 Litre unflavoured,
pH-neutral, macrogol 3350 bowel lavage.

| Detailed Product Description | |
|------------------------------|---------------|
| Macrogol 3350 | 59.00g |
| Sodium sulfate (anh) | 5.68g |
| Sodium bicarbonate | 1.69g |
| Sodium chloride | 1.46g |
| Potassium chloride | 750mg |
| Total Sodium | 2.87g |

ColonLYTELY Original solution is unflavoured.
Patient compliance may be improved as the solution can be modified by the glassful to the patient's taste, sweet or savoury.

ColonLYTELY Lemon 70g sachets
Macrogol with Electrolytes
Each sachet prepares a 1 Litre unflavoured,
pH-neutral, macrogol 3350 bowel lavage.

| Detailed Product Description | |
|------------------------------|---------------|
| Macrogol 3350 | 59.00g |
| Sodium sulfate (anh) | 5.68g |
| Sodium bicarbonate | 1.69g |
| Sodium chloride | 1.46g |
| Potassium chloride | 750mg |
| Total Sodium | 2.87g |

Also contains 'Nature Identical' Lemon Flavour and Sunett® acesulfame potassium sweetener.

References and explanations:

1. Polyethylene Glycol
2. Australian Medicines Handbook