Macrogol (PEG) 3350 with or without electrolytes – ENTERAL
Newborn Use Only

2023

Alert	The use of macrogol (PEG) 3350 with or without electrolytes is based on expert opinion with minimal studies assessing the safety and efficacy in the neonatal population. The electrolyte containing formulations should be dissolved in recommended amount of water to prepare an iso-osmolar solution.
Indication	To soften stool and assist with antegrade passage of stool through the bowel. In the NICU PEG should be prescribed in consultation with paediatric surgeon/paediatric gastroenterologist.
Action	Polyethylene glycol (PEG) is an osmotic agent causing retention of water in the stool resulting in a softer stool with more frequent bowel motions. An initial response is usually seen within 2-4 days. Macrogol is not significantly absorbed from the GIT.
Drug Type	Large polymer with osmotic activity.
Trade Name	1. **Macrogol (PEG) 3350 <u>with</u> electrolytes** Movicol 13.125g sachet Movicol Junior 6.9g sachet 2. **Macrogol (PEG) 3350 <u>without</u> electrolytes** ClearLax 17g sachet VivaLAX 17g sachet
Presentation	**Macrogol (PEG) 3350 <u>without</u> electrolytes** ClearLax 17g sachet (Herron) contains **macrogol 3350:** 17g VivaLAX 17g sachet contains **macrogol 3350:** 17g **Macrogol (PEG) 3350 <u>with</u> electrolytes** Movicol Junior 6.9g sachet contains **macrogol 3350:** 6.563g, NaCl 175.4mg, KCL 23.3 9mg, Na bicarbonate 89.3mg. Movicol 13.125g contains **macrogol 3350**: 13.125g, NaCl 350.7mg, KCL 46.6mg, Na bicarbonate 178.5mg per sachet
Dosage/Interval	Dose can vary based on indication and response. **Faecal impaction**: PEG with or without electrolytes orally 1-1.5g/kg/day for 3-6 days (maximum of 6 consecutive days).[1] **Maintenance:** PEG with or without electrolytes starting dose: 0.4g/kg/day, (dose range 0.2-0.8g/kg/day).[1]
Maximum Dose	1.5 g/kg/day
Preparation/Dilution	**As per individual sachet guidelines** ClearLax: dissolve 17g sachet in 200ml unchilled water. Movicol (13.125 g) : dissolve in 125 ml of unchilled water Movicol Junior (6.9 gm) : dissolve 6.9g sachet in 62.5ml of unchilled water
Administration	**Macrogol (PEG) 3350 – oral** Administer orally. Can be instilled into stoma directly if advised by Paediatric Gastroenterologist or Paediatric Surgeon.
Monitoring	May need electrolytes and fluid balance monitoring if prolonged or frequent use.
Contraindications	Hypersensitivity to any component, such as polyethylene glycol Bowel obstruction, known or suspected
Precautions	Can cause electrolyte imbalance with prolonged, frequent or excessive use Oral medications taken within an hour of administration may be flushed from the GIT without absorption
Drug Interactions	Nil

Adverse Reactions	Diarrhoea, especially at high doses Abdominal cramping, nausea, vomiting, abdominal distension Potential electrolyte disturbances with resultant fatigue, confusion, agitation, paraesthesia and muscle twitching Urticaria, suggestive of an allergic reaction has been reported
Compatibility	Not available
Incompatibility	Not available
Stability	Oral solution: Discard remaining after use.
Storage	Room temperature
Special Comments	Macrogol 3350 should not routinely be used in infants <6 months unless recommended by a Paediatric Gastroenterologist or Paediatric Surgeon.
Evidence summary	**Efficacy** The combination of PEG 3350 with electrolytes (PEG+E) has been shown to be effective for treating chronic constipation and faecal impaction in adults and children.[1-5] In a RCT In a RCT of 88 children with a mean age of 3.6 years, Jarzebicka compared a 12 week course of PEG 3350 with lactulose for management of functional constipation. At week 12, good clinical outcome was achieved in 98% (PEG) and 90% (lactulose). The PEG group had more defecations per week compared with the lactulose group (7.9 ± 0.6 vs 5.7 ± 0.5, P = 0.008) and both groups had similar frequency of defecation with pain (5% vs 5%, P = 0.9), stool retention (7% vs 10%, P = 057), large volume of stools (30% vs 31%, P = 0.9) and hard stools (7% vs 13%, P = 0.58). There were more patients with side effects in the lactulose group (15 vs 23, P = 0.02), mostly bloating and abdominal pain. Roy et al described a retrospective cohort of 477 infants < 6 months who were prescribed PEG+E for constipation and faecal impaction. The median weight of infants at prescription was 5.2 kg (IQR 4.6-5.9). In this cohort, 20% participants required only one treatment episode while 44% required two and 36% required more than two episodes of treatment. In 85% of the treatment episodes resolution of symptoms was achieved with a median daily dose of one sachet. The median duration of treatment during the first episode was about 100 days. **Safety** When the powder is dissolved in the correct volume of water, the resulting solution is iso-osmolar with respect to colonic extracellular fluid and therefore does not draw fluid into the colon from the body. In randomised control trials in children, adverse event rate was similar to placebo and most commonly involved mild abdominal discomfort.[3] In the retrospective cohort, Roy et al reported fatigue (60%), shortness of breath (26%), vomiting (11%), diarrhoea (10%), potential electrolyte disturbances (7%) and abdominal pain (2.5%) as the common adverse events related to PEG +E use.
References	1. Evaluation and treatment of functional constipation in infants and children: evidence-based recommendations from ESPGHAN and NASPGHAN. Tabbers MM1, DiLorenzo C, Berger MY, et al. J Pediatr Gastroenterology Nutr. 2014 Feb; 58(2):258-74. 2. Macrogol 3350 plus electrolytes for chronic constipation in children: a single-centre, open-label study. Hardikar W, Cranswick N, Heine R. J Paediatr Child Health. 2007 Jul-Aug; 43(7-8):527-31.

	3. Polyethylene glycol 3350 plus electrolytes for chronic constipation in children: a double blind, placebo controlled, crossover study. A Thomson, H Jenkins, W Bisset et al. Arch Dis Child 2007; 92:996–1000. 4. . 5. Jarzebicka D, Sieczkowska-Golub J, Kierkus J, et al. PEG 3350 Versus Lactulose for Treatment of Functional Constipation in Children: Randomized Study. J Pediatr Gastroenterol Nutr. 2019 Mar;68(3):318-324 6. Roy D, Akriche F, Amlani B, Shakir S. Utilisation and Safety of Polyethylene Glycol 3350 with Electrolytes in Children Under 2 Years: A Retrospective Cohort. J Pediatr Gastroenterol Nutr. 2021 May 1; 72(5):683-689 7. http://www.perrigo.com.au/upload/product/document/CLE03327F_HPRG.pdf.

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