

# **MiraLax**

### What is MiraLax?

MiraLax (Polyethylene Glycol 3350) is a highly effective stool softener with polyethylene glycol (PEG). Electrolyte-free PEG has no detectable taste but otherwise is similar to balanced salt solutions used for "cleanouts" prior to colonoscopy.

#### How does MiraLax work?

MiraLax is an osmotic laxative that works by increasing the water in the stool. It can be mixed with any beverage.

### How long will my child need MiraLax?

MiraLax is often used for months to years in a pediatric gastroenterology practice, even though the manufacturer's labeling suggests treatment periods for 5 days. Although MiraLax is marketed for short-term use, there are studies in children and adults confirming its safety and effectiveness for long-term use. Most children need MiraLax until they have overcome any fears of defecation and until they have developed better habits like eating a good diet and learning to use their sphincter muscles properly.

#### How safe is MiraLax?

MiraLax is safe and probably safer than most alternatives. Its active ingredient, PEG, is approved by the Food and Drug Administration (FDA) as a food additive. It is commonly used by the food industry as a coating, binding, and texture-improving agent. PEG 3350 (MiraLax) is absorbed in barely detectable amounts from the intestines when taken orally. When absorbed, it is excreted unchanged in the urine.

The most common side effect has been cramping or flatulence when fruit juices are consumed with MiraLax. Also MiraLax can cause diarrhea with higher doses.

## What is the best dosage of MiraLax?

Children often require larger doses than adults. The dose that causes a child to have large, soft to runny stools each day is the right dose. This often requires adjustment. Typically, one glass is considered to be one capful (17 grams) of MiraLax with 8 ounces of a beverage. Initial dose is as follows:

One year of age:	½ to ¾ glass per day	or	½ to ¾ capful
2 to 5 years of age:	1 to 1 ½ glasses per day	or	1 to 1 ½ capfuls
6 years and older:	1 ½ to 2 glasses per day	or	1 ½ to 2 capfuls

### Update on Miralax Safety – January 8, 2015

In 2015, a New York Times article described a study that is being performed in Philadelphia looking at the safety of Miralax; this study was prompted by concerns that Miralax (and similar medicines with the same active ingredient PEG 3350) could have impurities that could cause neurologic symptoms like tics or tremors.

The fact that there is another study of Miralax does not mean that Miralax should not be used. Here is what we know right now about Miralax and related medications:

- 1) There is potential for side effects with every medication. The alternatives to miralax, which include Mineral oil, senna, lactulose, phosphate enemas, milk of magnesia all have potential side effects. We only use medications when they are needed and when we believe that the potential benefit outweighs the potential harm.
- 2) Premature discontinuation of laxative use in children is often associated with symptom relapse and in the long term may be more harmful that prolonged use of laxatives.
- 3) PEG 3350 is one of the most studied medications ever in pediatric gastroenterology. It has been shown to be effective and safe for chronic constipation, for fecal disimpaction, and even at very high doses as prep for colonoscopy. It has been studied in different ages.
- 4) There are Cochrane reviews (Cochrane Review: Osmotic and stimulant laxatives for the management of childhood constipation. Gordon M, Naidoo K, Akobeng AK, Thomas AG. Evid Based Child Health. 2013 Jan;8(1):57-109) recommending its usage. In addition, major organizations, including American Gastroenterology Association and the North American Society for Pediatric Gastroenterology Hepatology and Nutrtion have issued societal position statements advocating use of PEG 3350 as first line treatment for constipation. These expert guidelines state that this agent is deemed more effective than other agents and as safe as other agents.
- 5) There is no current credible evidence in the pediatric literature to link use of PEG 3350 to autism or other neurologic problems. Many children with autism and neurologic problems and many children without these neurologic problems have problems with constipation.
- 6) Contaminants like diethyl glycol and ethylene glycol are found also in cosmetic products, medications, and other products.
- 7) Our physicians use Miralax for their own children and relatives.

**Conclusion:** While there are alternatives to Miralax/PEG 3350, none of them are known to be safer. For most children, not treating their constipation is much more dangerous than any of the medications that we recommend.