

miralax



THIS OVER-THE-COUNTER LAXATIVE IS APPROVED FOR 17+ YEAR OLDS TO TREAT OCCASIONAL CONSTIPATION OR IRREGULAR BOWEL MOVEMENTS

Miralax can cause:

- + Bloating
- + Blood in stool
- + Severe or bloody diarrhea
- + Nausea
- + Stomach cramps/pain
- + Vomiting
- + Abdominal distension/pain
- + Borborygmi (rumbling noise produced by the movement of gas through the intestines)
- + Flatulence
- + Abdominal cramping
- + Perianal (area around the anus) inflammation/soreness
- + Allergic reaction
- + Urticaria (hives)
- + Excessive stool frequency
- + Rectal bleeding
- + Dizziness
- + Increased sweating

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long term carcinogenicity studies, genetic toxicity studies and reproductive toxicity studies in animals have not been performed with MiraLax.

Pregnancy: Category C. Animal reproductive studies have not been performed with MiraLax. It is also not known whether MiraLax can cause fetal harm when administered to a pregnant woman, or can effect reproductive capacity. MiraLax should only be administered to a pregnant woman if clearly needed.

Pediatric Use: Safety and effectiveness in pediatric patients has not been established.

Geriatric Use: There is no evidence for special considerations when MiraLax is administered to elderly patients. In geriatric nursing home patients a higher incidence of diarrhea occurred at the recommended 17 g dose. If diarrhea occurs MiraLax should be discontinued.

Unfortunately, most of the Miralax manufacturer insert on the FDA website has been photocopied (example above) and heavily redacted, therefore the following slides have been transcribed versus copy/pasted.

SOURCES FROM FDA + BRAINTREE LABORATORIES, INC.

WHAT IS MIRALAX

Miralax is a laxative solution that increases the amount of water in the intestinal tract to stimulate bowel movements. The active ingredient is **Polyethylene Glycol 3350** and is used as an osmotic laxative. Osmotic laxatives draw water into the lumen (interior surface) of the bowel. To produce a bowel movement, two-four days may be required.

Osmotic laxatives also result in volume load therefore Miralax should not be used if you have a bowel obstruction or intestinal blockage. If you have any of these conditions, you could have dangerous or life-threatening side effects. Miralax should not be used for longer than two weeks. Prolonged, frequent or excessive use may result in electrolyte imbalance and dependence on laxatives.

Long-term carcinogenicity studies, genetic toxicity studies, and reproductive toxicity studies in animals have not been performed with Miralax.

Animal reproductive studies have not been performed with Miralax. **It is also not known whether Miralax can cause fetal harm when administered to a pregnant woman, or can effect reproductive capacity.** Miralax should only be administered to a pregnant woman if clearly needed.



MIRALAX + CHILDREN

according to the manufacturer:

Safety and effectiveness in pediatric patients has not been established. Miralax **should not** be used by children.

Who Should NOT take MiraLax
MiraLax should not be used by children. It should not be used by pregnant women unless prescribed by a physician.

according to the fda:

October - December 2020 | Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System (FAERS)

Product Name: Trade (Active Ingredient) or Product Class	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of March 23, 2021)
GoLytely (polyethylene glycol 3350 and electrolytes) MiraLAX (polyethylene glycol 3350) MoviPrep (polyethylene glycol 3350, ascorbic acid, sodium ascorbate, sodium chloride, sodium sulfate, and potassium chloride) NuLytely (polyethylene glycol 3350, potassium chloride, sodium bicarbonate, sodium chloride and sodium sulfate) Plenvu (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride)	Aspiration	FDA is evaluating the need for regulatory action.

<https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/october-december-2020-potential-signals-serious-risksnew-safety-information-identified-fda-adverse>

NEUROPSYCHIATRIC EVENTS

according to the fda:

October - December 2011 | Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS)

Product Name: Active Ingredient (Trade) or Product Class	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of March 1, 2014)
Polyethylene Glycol (PEG) 3350 over-the-counter oral laxative (Miralax)	Neuropsychiatric events	FDA decided that no action is necessary at this time based on available information.

The FDA awarded a \$324k grant in 2014 to Children's Hospital of Philadelphia (CHOP) to study "Polyethylene Glycol Safety in Children." The study is ongoing.

Why is this product recommended off-label by healthcare providers when there is an ongoing study on its safety in the pediatric population?

https://taggs.hhs.gov/Detail/AwardDetail?arg_AwardNum=R01FD005312&arg_ProgOfficeCode=1

Although PEG 3350 is only approved by the U.S. FDA for use in people =17 years of age for no more than seven days, this medicine is very commonly used in young children, often at adult doses, for months or years at a time. The safety of PEG 3350 use by children or for prolonged periods is not known. Furthermore, although PEG 3350 is a polymer that is poorly absorbed, batches of this medicine tested by the FDA have been found to contain small amounts of low molecular weight compounds (e.g. ethylene glycol and diethylene glycol) that might be absorbed and are known to be toxic in high enough doses. Finally, some families who have given PEG 3350 to their children have reported symptoms to the FDA that they are concerned may have been caused by PEG 3350 ingestion. In particular, there is a concern that PEG 3350 components might cause neurobehavioral symptoms.

WHAT IS CONSTIPATION



Constipation is a condition in which you may have fewer than three bowel movements a week; stools that are hard, dry, or lumpy; stools that are difficult or painful to pass; or a feeling that not all stool has passed. You usually can take steps to prevent or relieve constipation.

However, people can have different bowel movement patterns, and only you know what's normal for you.

Constipation is not a disease, but may be a symptom of another medical problem. Constipation may last for a short or long time.

<https://www.niddk.nih.gov/health-information/digestive-diseases/constipation/definition-facts>

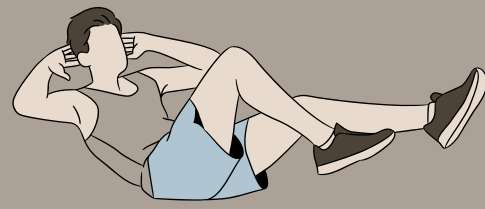


HOW TO TREAT CONSTIPATION

according to the manufacturer:

Patients should be educated about good eating habits such as high fiber diets. Lifestyle changes such as adequate dietary fiber/fluid intake and regular exercise may produce more regular bowel habits.

NIH National Institute on Aging



What you eat, drink, and do can also contribute to constipation. For example:

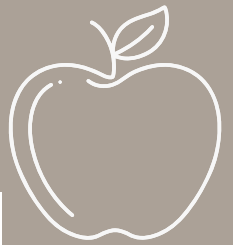
- **Not enough fiber.** You may become constipated if you don't eat enough high-fiber foods, such as [vegetables](#), [fruits](#), and whole [grains](#). Eating a lot of high-fat meats, [dairy products](#) and eggs, sweets, or processed foods may cause constipation.
- **Not enough fluids.** Water and other fluids help fiber work better, so not drinking enough liquids can contribute to harder stools that are more difficult to pass.
- **Lack of physical activity.** Not getting enough exercise or long periods of inactivity due to illness or following surgery may cause constipation.
- **Changes in routine.** Altering your daily routine — traveling, for example — can cause constipation.

<https://www.nia.nih.gov/health/concerned-about-constipation>

CONSTIPATION IN CHILDREN

NIH NIDDK

Depending on your child's age and sex, he or she should get 14 to 31 grams of fiber a day.² Fiber guidelines are not available for infants less than 1 year old. Your child's doctor can tell you what kinds of foods your child should eat. If your child is on a formula or breast milk,



Parents Against Miralax

Restoralax Movicol (PEG 3350)

- legumes, such as lentils, black beans, kidney beans, soybeans, and chickpeas
- fruits, such as berries, apples with the skin on, oranges, and pears
- vegetables, such as carrots, broccoli, green peas, and collard greens
- nuts, such as almonds, peanuts, and pecans



If your child is dehydrated, have your child drink plenty of water and other liquids, such as naturally sweetened fruit and vegetable juices and clear soups, to help the fiber work better.

Changing your child's bowel movement patterns and behaviors may help treat constipation.

- Ask your potty-trained child to use the toilet after meals to build a routine.
- Use a reward system when your child uses the bathroom regularly.
- Take a break from potty training until the constipation stops.

<https://www.niddk.nih.gov/health-information/digestive-diseases/constipation-children/eating-diet-nutrition>

To help prevent or relieve constipation, your child should avoid foods with little to no fiber, such as

- chips
- fast food
- meat
- prepared foods, such as some frozen meals and snack foods
- processed foods, such as hot dogs or some microwavable dinners

For a supportive community discussing personal experiences with this product, click on the images or link below:

**Parents Against Miralax
Restoralax Movicol (PEG 3350)**

We are a group of parents and family members who are very suspicious of PEG 3350 and are here to discuss its effects on our children. We discuss alternative options, focusing on healing the gut naturally, and ways to talk to doctors about our opposition to this very dangerous drug. We are not a replacement for the type of health care you choose, we only speak from experience.

<https://www.facebook.com/groups/209540745755798/>