WHAT IS IN MIRALAX® (A BRAND NAME FOR A POPULAR PRODUCT) AND SIMILAR LAXATIVES?

- The ingredient is called PEG 3350 (or PEG 4000), which is short for polyethylene glycol.

WHY ARE SOME PEOPLE WORRIED ABOUT THESE PEG 3350 LAXATIVES?

- Some parents have noticed behavior changes in their children that they think happened after using PEG 3350.
- The product directions are only written for adults, and state to use for “no more than 7 days.”
- “Polyethylene glycol” sounds like some known toxic chemicals called ethylene glycol and diethylene glycol.
- Some news stations and internet blogs have run sensational stories about claims of toxicity.

THOSE CONCERNS SOUND SERIOUS. SHOULD WE BE WORRIED?

- Behavior problems often start in childhood, and constipation is often a first symptom. It is not surprising that some children might be taking a laxative when behavior problems get recognized.
- PEG 3350 has been studied in children and is often considered the best drug for constipation (see next page). Many children have been treated for months to years.
- Polyethylene glycol is different, chemically, than ethylene glycol or diethylene glycol. Polyethylene glycol is used in lots of personal care products and many other medicines.
- No medicine (not even the pain medicine ibuprofen or the antibiotic amoxicillin) is 100 percent safe. PEG 3350 seems to be one of the safest medicines and has been used safely in millions of children over the past 20 years.

WHAT DOES THE POISON CONTROL CENTER RECOMMEND?

- Any medication should be used for the shortest amount of time, and at the lowest effective dose, possible.
- Talk to your healthcare provider about ways to prevent and treat constipation without medications:
  - Keep well-hydrated.
  - Eat a diverse and well-balanced diet with plenty of natural fiber and whole grains.
  - Avoid processed foods as much as possible.
  - Get daily exercise.
  - Reduce stress and pressure around toilet time.
  - Develop good bowel habits and a regular toilet routine.
- If medication is needed to help treat constipation, PEG 3350 may still be the best choice.
- There are alternatives to PEG 3350 — talk to your nurse or doctor to learn more.
- If you think your child may have been harmed by PEG 3350: a) stop giving your child the drug, b) tell your nurse or doctor, and c) file a report with the FDA at https://www.fda.gov/Safety/MedWatch/HowToReport.

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RESOURCES:
24-HOUR HOTLINE
1-800-222-1222
CHOP.EDU/POISONCONTROL
A SAMPLE OF STUDIES LOOKING AT PEG 3350 (OR PEG 4000) LAXATIVES IN CHILDREN

“Polyethylene Glycol 4000 for Treatment of Functional Constipation in Children”
*Journal of Pediatric Gastroenterology and Nutrition, 2015*
- Gave 90 children, ages 1 to 13 years, either “high-dose” or “low-dose” laxative for 6 weeks
- Treatment seemed safe, no major differences were seen when using high or low doses

“A Randomised, Double-Blind Study of Polyethylene Glycol 4000 and Lactulose in the Treatment of Constipation in Children”
*BMC Pediatrics, 2014*
- Studied 88 children, ages 12 to 36 months, for 4 weeks of treatment
- No behavioral problems were reported. Researchers felt the PEG 4000 worked better than lactulose

“PEG 3350 in the Treatment of Childhood Constipation: A Multicenter, Double-Blinded, Placebo-Controlled Trial”
*Journal of Pediatrics, 2008*
- Studied 103 children, ages 4 to 16 years, for two weeks of treatment
- Treatment seemed safe; no behavioral problems were reported among children getting laxative
- Important note: 1 child had worsening of his psychiatric illness, but he was NOT getting laxative (only placebo)

“Double-Blind Randomized Evaluation of Clinical and Biological Tolerance of Polyethylene Glycol 4000 Versus Lactulose in Constipated Children”
*Journal of Pediatric Gastroenterology and Nutrition, 2005*
- Followed 96 children, ages 6 months to 3 years, for 3 months of treatment
- Treatment seemed safe, no behavioral problems were reported, and the PEG 4000 seemed better than lactulose

“Polyethylene Glycol for Constipation in Children Younger than Eighteen Months Old”
*Journal of Pediatric Gastroenterology and Nutrition, 2004*
- Looked at 28 children, ages 0 to 18 months, treated for an average of 6 months
- Treatment seemed safe; no behavioral problems were reported

“PEG 3350 versus Lactulose in the Treatment of Childhood Functional Constipation: A Double-Blind, Randomised, Controlled, Multicentre Trial”
*Gut, 2004*
- studied 91 children, ages 6 months to 15 years, for 8 weeks
- Unfortunately, nine children entered the study, but did not finish, for unreported reasons
- No behavioral problems were reported; researchers felt the PEG 3350 worked better than lactulose

“Long-term Efficacy of Polyethylene Glycol 3350 for the Treatment of Chronic Constipation in Children with and Without Encopresis”
*Clinical Pediatrics, 2003*
- Looked at 74 children, ages 2 to 17 years, for up to 30 months of treatment
- No behavioral problems were reported

“No Safety of Polyethylene Glycol 3350 for the Treatment of Chronic Constipation in Children”
*Archives of Pediatric and Adolescent Medicine, 2003*
- Followed 83 children, ages 2 to 17 years, for an average 9 months of treatment
- Treatment seemed safe, no behavioral problems were reported