DESCRIPTION
A white powder for reconstitution. MiraLax (polyethylene glycol 3350, NF) is a synthetic polyethylene having an average molecular weight of 3350. The actual molecular weight is not less than 90.0 percent and not greater than 110.0 percent of the nominal value. The chemical formula is HO(C₂H₄O)₈H₂ in which n represents the average number of oxyethylene units. Below 55°C it is a free-flowing white powder freely soluble in water.

MiraLax is an osmotic agent for the treatment of constipation.

CLINICAL PHARMACOLOGY
Pharmacology: MiraLax is an osmotic agent which causes water to be retained with the stool.

Essentially, complete recovery of MiraLax was shown in normal subjects without constipation. Attempts at recovery of MiraLax in constipated patients resulted in incomplete and highly variable recovery. In vitro study showed indirectly that MiraLax was not fermented into hydrogen or methane by the colonic microflora from human feces.

MiraLax appears to have no effect on the active absorption or secretion of glucose or electrolytes. There is no evidence of tachyphylaxis.

CLINICAL TRIALS
In one study, patients with less than 3 bowel movements per week were randomized to MiraLax, 17 grams, or placebo for 14 days. An increase in bowel movement frequency was observed for both treatment groups during the first week of treatment. MiraLax was statistically superior to placebo during the second week of treatment.

In another study, patients with 3 bowel movements per week were randomized to 2 dose levels of MiraLax or placebo for 10 days each. Success was defined by an increase in both bowel movement frequency and daily stool weight. Both parameters, superiority of the 17 gram dose of MiraLax over placebo was demonstrated.

INDICATIONS AND USAGE
For the treatment of occasional constipation. This product should be used for 2 weeks or less as directed by a physician.

CONTRAINDICATIONS
MiraLax is contraindicated in patients with known or suspected bowel obstruction and patients known to be allergic to polyethylene glycol.

WARNINGS
Patients with symptoms suggestive of bowel obstruction (nausea, vomiting, abdominal pain or distension) should be evaluated to rule out this condition before initiating MiraLax therapy.

PRECAUTIONS
General: Patients presenting with complaints of constipation should have a thorough medical history and physical examination to detect associated metabolic, endocrine and neurogenic conditions, and medications. A diagnostic evaluation should include a structural examination of the colon.

Patients should be educated about good dietary habits (such as high fiber diets) and lifestyle changes (adequate dietary fiber and fluid intake, regular exercise) which may produce more regular bowel habits.

MiraLax should be administered dissolved in approximately 8 ounces of water.

Information for Patients: MiraLax softens the stool and increases the frequency of bowel movements by retaining water in the stool. It should always be taken by mouth after being dissolved in 8 ounces of water. Should unusual cramps, bloating, or diarrhea occur, consult your physician.

Two to 4 days may be required to produce a bowel movement. This product should be used for 2 weeks or less as directed by a physician. Prolonged, frequent or excessive use of MiraLax may result in electrolyte imbalance and dependence on laxatives.

Laboratory Tests: No clinically significant effect on laboratory tests have been demonstrated.

Drug Interactions: No specific drug interactions have been demonstrated.

Growth, 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 not known whether MiraLax can cause fetal harm when administered to a pregnant woman, or can affect 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.

ADVERSE REACTIONS
Nausea, abdominal bloating, cramping and flatulence may occur. High doses may produce diarrhea and excessive stool frequency, particularly in elderly nursing home patients.

Patients taking other medications containing polyethylene glycol have occasionally developed urticaria suggestive of an allergic reaction.

OVERDOSE
There have been no reports of accidental overdose. In the event of overdose diarrhea would be the expected major event. If an overdose of MiraLax occurs without concomitant ingestion of fluid, dehydration due to diarrhea may result. Medication should be terminated and free water administered. The oral LD₅₀ is >50 gm/Kg in mice, rats and rabbits.

255 grams
DOSEAGE AND ADMINISTRATION
The usual dose is 17 grams (about 1 heaping tablespoon) of powder per day (or as directed by physician) in 8 ounces of water. Each bottle of Miralax is supplied with a measuring cap marked to contain 17 grams of laxative powder when filled to the indicated line.
Two to 4 days (48 to 96 hours) may be required to produce a bowel movement.

HOW SUPPLIED
In powdered form, for oral administration after dissolution in water. Miralax is available in two package sizes, a 14 oz. container of 255 grams of laxative powder and a 26 oz. container of 527 grams of laxative powder.
The cap on each bottle is marked with a measuring line and may be used to measure a single Miralax dose of 17 grams (about 1 heaping tablespoon).

Rx only

STORAGE
Store at 25 degrees C (77 degrees F); excursions permitted to 15-30 degrees C (59-86 degrees F). See USP “Controlled Room Temperature.”

Distributed by Braintree Laboratories, Inc., Braintree, MA 02185

PATIENT INFORMATION
Miralax® (Polyethylene Glycol 3550, NF Powder) is a prescription only laxative which has been prescribed by your doctor to treat constipation. This product should only be used by the person for whom it was prescribed.

How to take
The dose is 17 grams each day or as directed by physician. It should always be taken by mouth. Measure the dose using the measuring cap (or use one heaping tablespoon of powder), stir and dissolve in a glass (8 oz) of water. Taking more than the prescribed dose may cause loss of fluid due to severe diarrhea.

How will it work
Miralax softens the stool and increases the frequency of bowel movements by retaining water in the stool. Your first bowel movement will usually happen in two to four days, although results may vary for individual patients.

How long should I take it
Miralax achieves its best results when used between one and two weeks. You may discontinue taking the drug after you have had several satisfactory bowel movements. If unusual cramps, bloating, or diarrhea occur, consult your physician. Miralax is intended for use up to a two week course of therapy. You should not use for a longer time unless directed by your doctor.

Next Steps
After successfully completing the Miralax therapy (usually between one and two weeks) please discuss with your doctor lifestyle changes which may produce more regular bowel habits (adequate dietary and fluid intake, regular exercise).

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.

Side Effects/Drug Reactions
Occasionally, Miralax may cause nausea, stomach fullness, cramping, diarrhea and/or gas. Do not take if you have symptoms such as nausea, vomiting, abdominal pain or distention, which may be due to bowel obstruction. On rare occasions hives and skin rashes have been reported which are suggestive of an allergic reaction. If you get an allergic reaction you should discontinue the medication and call your doctor.

If you are allergic to polyethylene glycol, do not use this drug.
Prescription Laxative

MiraLax®
Polyethylene Glycol 3350, NF Powder

This bottle contains
527 grams of polyethylene glycol 3350, NF powder

Licensed Under U.S. Patent No. 5,710,183

Distributed by
Braintree Laboratories, Inc.
Braintree, MA 02185

Directions
1. Note: the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line.
2. Daily dose is 17 g per day or as directed by physician.
3. Pour 17 g (about 1 heaping tablespoon) of powder into the cap of the bottle.
4. Dissolve the powder in a cup (8 oz) of water.
5. Drink the solution.
6. Treatment for 2 to 4 days may be required to produce a bowel movement.

Pour only
Keep this and other drugs out of reach of children.
Store at 25°C (77°F)

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