

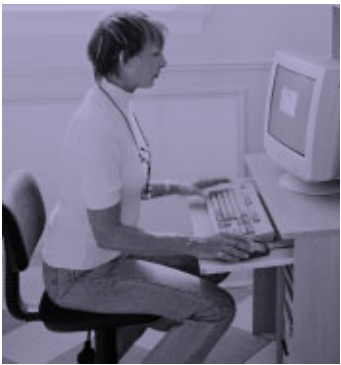
BEST BUY DRUGS



Evaluating Drugs Used to Treat:

Constipation

Comparing Effectiveness, Safety, and Price



Our Recommendations

Constipation is very common. Like headaches and colds, almost everyone will experience a bout at some point. For most, these episodes are brief and usually don't require medical treatment. But doctors start to get concerned if the frequency of your bowel movements drops below three per week for two weeks or longer. At any one time, an estimated 35 to 45 million people in the U.S. are in that predicament, or have been diagnosed with chronic constipation or a condition called Irritable Bowel Syndrome (IBS).

If you are constipated, the first thing to do is eat more fiber-rich foods such as vegetables, fruits, whole grains, legumes, and beans. If that doesn't work, try a fiber supplement. Our analysis found that those containing psyllium are best. If your constipation persists for two weeks or longer, you may need a drug. A variety are available, both nonprescription and prescription. These include stool softeners and different types of laxatives. The vast majority of people will get the help they need from inexpensive, nonprescription drugs.

Taking cost and the evidence for effectiveness and safety into account, we chose the nonprescription drug polyethylene glycol (MiraLax) as our *Best Buy*. This drug improves constipation symptoms and is just as effective as a prescription drug called lactulose. In addition, it has a track record of being safe and well tolerated by most people. We caution against the long-term use (beyond a few days) of the laxatives senna (Senokot, Ex-Lax) and bisacodyl (Correctol, Doxidan, Dulcolax). Studies indicate these drugs are less effective for relieving chronic constipation.

If you're unable to tolerate MiraLax or it doesn't improve your symptoms, you should talk to your doctor about other options, which may include generic lactulose or lubiprostone (Amitiza). Warning: Amitiza is a new and expensive prescription drug which may be no more effective than MiraLax or lactulose for most people and its safety profile is not fully established.

Amitiza is also approved for women who have IBS with constipation as the main symptom (and many doctors will prescribe it for men, too). But we advise people with this condition to talk to their doctors about trying other medicines first, in addition to lifestyle changes, and only consider Amitiza if these strategies fail to provide relief.

This report was released in December 2008.

Welcome

This report compares the effectiveness, safety, and cost of medicines used to treat constipation – when it occurs on its own and when it is part of a condition called irritable bowel syndrome (IBS). It draws chiefly on 34 studies that evaluated and compared the effectiveness and/or safety of constipation drugs.

This report is part of a Consumers Union and *Consumer Reports* project to help you find medicines that are safe and effective and give you the most value for your health care dollar. To learn more about the project and drugs we have evaluated for other diseases and conditions, please visit www.ConsumerReportsHealth.org/BestBuyDrugs.

Constipation is a delicate topic. Many people are even reluctant or embarrassed to talk to their doctors about it. We have tried in this report to use language that won't offend but is blunt enough to make the information clear.

As you might imagine, constipation is quite common. Like headaches and colds, almost everyone will experience a bout at some point. In the vast majority of cases, these episodes don't last long, go away on their own and may not require any treatment. You should also know that occasionally going a day or two without a bowel movement is not that unusual and usually does not require a visit to a doctor or warrant a diagnosis of clinical constipation – though it's certainly common to describe the experience as “being a little constipated.” Indeed, there's no established frequency of bowel movements that separates healthy from unhealthy. People vary. Some people go two or three times per day like clockwork while others have a bowel movement only once per day or once every two days. In general, doctors start getting concerned if your frequency drops below three bowel movements a week, especially if that represents a change from your previous pattern and if it goes on for two weeks or longer.

At any one time, an estimated 35 to 45 million people in the U.S. fit that definition. All should be getting medical attention since the experience can be uncomfortable, unnerving, and affect quality of life. But they also need attention because untreated constipation can be dangerous. For example, it can lead to hemorrhoids, anal fissures (painful tears in the lining around the anus) and fecal impaction (when your stools become so hard that they will not pass on their own.)

Three groups of people are more prone to constipation than others – (a) seniors, because bowel activity naturally slows down as we age and because seniors are more likely to be taking drugs that can cause constipation (see page 8); (b) children, because they may hold their bowel movements due to shyness or to avoid using public toilets; and (c) pregnant women, because hormonal changes during pregnancy can affect the mus-

cles that line the intestines and because the expanding womb can place pressure on the intestines. Iron tablets, which many pregnant women take, can also cause constipation. (Indeed, women in general are more than twice as likely as men to experience constipation.)

If you have constipation or occasionally suffer from it, the question of when to see a doctor is important. Most people with a transient bout of constipation don't need to see a doctor, but you should if any of the following occur:

- If your bowel movements have fallen to less than three per week for 2 weeks or longer.
- If you have periodic and recurring episodes when you go 3 to 4 days without a bowel movement
- If you are “irregular” – say, with episodes of frequent bowel movements followed by 3-4 days without one
- If you often have feelings of abdominal bloating, cramping and discomfort
- If you have blood in your stools or it's black or tarry-looking
- If you experience pain when you have a bowel movement
- If you have persistent or recurring abdominal pain
- If there is a sudden and sharp change in how often you move your bowels
- If you often have to strain during bowel movements and/or it takes a long time to have one
- If your stools are hard (rocky or pellet-like)
- If your stools become very thin for more than a few days (a possible indicator of colon cancer)
- If you often have a sensation of incomplete evacuation after bowel movements
- If over-the-counter treatments have failed to relieve your symptoms

Some Basics on Constipation

To understand how constipation develops, it helps to know how your large intestine, or colon, works. Muscles in the walls of your bowels propel the “waste” through your intestines after food is digested. As this happens, water is reabsorbed, forming a solid stool. But if too much water is reabsorbed or the nerves or muscles in the intestinal walls are not functioning properly, the stool can become hard, dry and difficult to pass, resulting in constipation.

There are several types of constipation, linked to varying causes. By far the most common occurs when a person's “waste management” plumbing is working just fine but they are not getting enough dietary fiber. To function optimally, the intestine needs a steady supply of bulk material (sometimes called “roughage”) to process. This gives the powerful intestinal

Table 1. The Drugs We Evaluate In This Report

Generic Name	Selected Brand Name(s)	Type of Drug	Available as a Generic?	Available as an Over-the-Counter Drug?
Alvimopan	Entereg	Opioid receptor antagonist	No	No
Bisacodyl	Correctol, Doxidan, Dulcolax	Laxative	Yes	Yes
Psyllium, Guar gum, Methylcellulose	Metamucil, Fiberall, Genfiber, Benefiber, Citrucel, FiberCon	Fiber supplement	Yes	Yes
Docusate	Colace, Regular, Sulfolax	Stool softener	Yes	Yes
Lactulose	Cephulac, Constulose, Kristalose, Duphalac	Laxative	Yes	No
Lubiprostone	Amitiza	Laxative	No	No
Methylnaltrexone	Relistor	Opioid receptor antagonist	No	No
Polyethylene glycol	MiraLax, Glycolax	Laxative	Yes	Yes
Senna (Sennosides)	Senokot, Ex-Lax	Laxative	Yes	Yes
Tegaserod	Zelnorm*	Serotonin receptor agonist	No	No

* Zelnorm is no longer available to most patients. It can only be obtained through a special request to the FDA for people who have constipation conditions that are life-threatening or serious enough to require hospitalization.

muscles something substantial to propel through the system. If the diet does not contain enough fiber, the stools can be drier and harder and stall on their way through the colon. And constipation is the outcome. Fiber is contained in vegetables, fruits, legumes, whole grains, and beans.

A second common cause of constipation – especially for busy people on the go – is ignoring the urge to have a bowel movement. This is a no-no that can, over time, lead to irregularity and chronic constipation.

A third type is called “slow transit” constipation. This occurs when -- for various reasons, including age, disease, or side effects of medications -- the colon does not move the stool along at the proper rate, so too much water gets reabsorbed. This results in dry, hard stools that are difficult to pass. A fourth type of constipation is called obstructed defecation or pelvic floor dysfunction. In this condition, the muscles in the pelvis and around the anus that help you pass stools are not working the way they should; they clinch up when they should be relaxing. Generally, this condition is

Table 2. Common Causes of Constipation

Diet low in fiber – Fiber makes stools softer, bulkier and easier to pass. Foods high in fiber include fruits, vegetables, beans, legumes, and whole grains.

Pregnancy – Constipation is a common problem for women during and after pregnancy. About half get it. Natural increases in the hormones estrogen and progesterone, as well as increased pressure on a mother's bowels from carrying the baby can both affect regularity in passing stools.

Age – Constipation is more common in older people. This is in part because slowing of the bowel functions is a natural part of the aging process and because the elderly are often on medications that slow the gastrointestinal tract.

Changes in routine – Many people become constipated while traveling, especially when it involves large time zone differences. Whether for business or pleasure, travel usually involves changes in your regular daily eating and sleeping habits, physical activity, and toilet routines. These changes can affect your metabolism and result in constipation.

Medicines – Constipation is a common side effect of many prescription and over-the-counter drugs. Some prescription drugs commonly known to cause constipation include pain killers, antidepressants, high blood pressure pills, and drugs to treat Parkinson's Disease. See Table 3 on page 8.

not helped by drugs or lifestyle changes. Instead, a technique called biofeedback is used to retrain the muscles to work properly.

Constipation can also be the main symptom of a condition called irritable bowel syndrome (IBS). IBS can be tough to diagnose because the symptoms range and can shift over time. Some people with IBS experience diarrhea, abdominal bloating, and/or cramps. Others mostly have constipation. And some can alternate between these sets of symptoms. People with IBS also often have recurrent or chronic abdominal pain.

Unfortunately, the cause of IBS is not well understood. Some experts think the pain and discomfort of IBS may occur because the gastrointestinal tract of patients with it are extra sensitive to stretch and distention. Another theory is that the muscles and nerves work too quickly in some patients, causing diarrhea, or too slowly in other patients, causing constipation.

Finally, constipation is also a common side effect of many medicines. Morphine and other “opioid-based” painkillers (for example, oxycodone, codeine, Vicodan, Percocet, and Dilaudid) are the worst offenders. Most people who take such medicines, even over a short period, will experience constipation. Opioids cause constipation by slowing down bowel function, leading to increased water absorption in the colon and ultimately drier, harder stools that are difficult to pass.

Many other medicines are guilty, too. These include certain antidepressants, cholesterol-lowering drugs, and over-the-counter painkillers. (See Table 3 on page 8).

This report was released in December 2008.



Who Needs Constipation Drugs?

Doctors usually follow a step-by-step approach to the treatment of constipation. And you should, too. First, if you have occasional, infrequent bouts, you probably don't need to take any medicines or (as we said in the Welcome section) see a doctor. Rather, your first step should be a more conservative approach that involves (a) adjusting your eating habits to include more fiber-rich foods, (b) sticking to a regular bathroom schedule, and (c) not ignoring or putting off the urge to go. Let nature take its course even if the timing is not particularly convenient.

It's best to start trying to get more fiber in your diet by increasing your intake of foods high in fiber. But, as you probably know, fiber can also be obtained from nonprescription supplements too. So if diet changes alone don't do the trick, taking a fiber supplement can be effective, and is the typical next step. We recommend fiber supplements that contain psyllium since it's the active ingredient that's been studied the most in treating chronic constipation. While the available studies evaluating psyllium are not conclusive, they suggest it increases the frequency of bowel movements by at least one to two per week on average when compared with placebo (for example, from 3 movements to 4 or 5). So, don't expect miracles. Metamucil is the best known brand containing psyllium but there are generic versions that may be less expensive at your local pharmacy or food store. Read the ingredients list to make sure you are buying a psyllium supplement.

While you're at it, read the directions carefully, too. Taking too much of a fiber supplement when you first start (a common mistake) can lead to cramping, bloating, and gas. Always start with the recommended low dose – typically 1 rounded tablespoon -- and increase it gradually over time as needed. If one type of psyllium supplement is causing you problems, try another. People respond to them differently. Be aware, too, that some fiber supplements contain sugar (Metamucil, for instance), which may not be suitable for people with diabetes.

While there's little research supporting increased fluid intake as an antidote to constipation, it's also worth a try and can't hurt. (Indeed, many people

don't routinely drink enough liquid.) If you take fiber supplements, drinking plenty of water is even more advisable. Exercise also is often recommended as a potential remedy, but the available research suggests it provides little, if any, benefit.

If lifestyle changes and fiber supplements don't resolve your constipation problem, it may be time to try a drug. But which one? As you saw from the list on page 5, and there's more detail in Table 4 on page 10, a variety of drugs are available. Most can be purchased over-the-counter without a prescription, but two are available by prescription only. A couple of others are used only in hospitals for severe cases of constipation.

After fiber supplements, *stool softeners* are one possible next step in treatment. Examples are Colace and Regulan, both of which contain an active ingredient called docusate (with either sodium or calcium). This drug helps retain water with the stool and soften it. While there aren't any rigorous studies showing how effective stool softeners are in relieving chronic constipation, they are considered to be safe when taken as directed, and they can be useful in preventing constipation from developing when short-term use of medications, such as narcotic pain relievers after surgery, is unavoidable.

Laxatives Explained

Laxatives are another option and there are several different types. *Saline laxatives* are magnesium-based drugs and are best known as "milk of magnesia." Others contain sodium phosphate or "phosphor-soda". They draw water into the colon and soften the stool. But restrictions apply to their use. Extended use of saline laxatives can lead to electrolyte imbalance, especially in children, and they should not be used at all by people with kidney problems. The FDA recently added a warning to the labeling of two prescription oral sodium phosphate products – Visicol and Osmoprep that are used prior to colonoscopy and other procedures – cautioning that they can cause kidney damage. The agency said it is concerned about similar products that are available without a prescription but noted that when they are used at the lower doses for laxative purposes there does not appear to be a risk of kidney injury.

Table 3. Drugs That Can Cause Constipation*

Medicine	Examples
Opiates	codeine, Dilaudid, morphine, Percocet, Vicodin
Anticholinergics, antispasmodics, and Antidiarrheal medications	alosetron, dicyclomine, oxybutynin, propantheline, tolterodine
Tricyclic antidepressants	amitriptyline (Elavil), imipramine, nortriptyline
Calcium channel blockers	diltiazem (Cardizem), amlodipine (Norvasc), verapamil
NSAIDs	ibuprofen (Motrin, Advil), naproxen (Aleve, Naprosyn)
Antiparkinsonian drugs	benztropine, carbidopa, levodopa, trihexyphenidyl
Decongestants	pseudoephedrine (Sudafed)
Antipsychotics	haloperidol (Haldol), risperidone (Risperdal), olanzapine (Zyprexa)
Cholesterol-lowering drugs	cholestyramine, colestipol
Diuretics	furosemide (Lasix), hydrochlorothiazide
Anticonvulsants	phenytoin (Dilantin), valproic acid (Depakene)
Calcium supplements	calcium citrate, calcium carbonate (OsCal)
Iron supplements (including multivitamins with iron)	ferrous fumarate, ferrous gluconate, ferrous sulfate
Antacids containing calcium or aluminum	Maalox, Mylanta, Roloids, Tums

* Not intended to be a comprehensive list.

So-called *stimulant laxatives* include such drugs as senna (sometimes called the sennosides; Ex-Lax, Senokot, other brands and generics) and bisacodyl (Dulcolax, Correctol, Bisa-Lax, other brands and generics). These drugs stimulate the muscles of the intestines to move the stool along. That rapid movement, which can cause cramping, lessens water absorption and softens the stool. These drugs can help alleviate single episodes of constipation, but they don't help improve chronic constipation and are not recommended for long-term use (more than 2 days).

One final group of laxatives is called the *osmotic laxatives*. The most common ones are based on either the active ingredient lactulose (various brands and generics) or polyethylene glycol (MiraLax, Glycolax,

and generics). In 2006, MiraLax became the only polyethylene glycol product available over-the-counter and is now commonly available at pharmacies, grocery stores and other outlets without a prescription.

Note that in this report we do not discuss or evaluate two other old-time laxatives: mineral oil and castor oil. Use of these has gone out of style because the unpleasantness of taking them outweighs any benefit and because other medicines have eclipsed them.

The Rx Only Drugs

The two prescription-only medicines used to treat constipation are lactulose (Kristalose, Cephulac, Enulose, etc.) and lubiprostone (Amitiza). Amitiza is

a relatively new drug that causes the cells that line the intestines to secrete chloride, sodium and water to help soften stools. The FDA approved it in 2006 to treat chronic constipation. In 2008, the agency also approved Amitiza to treat irritable bowel syndrome (IBS) in women whose main symptom is constipation.

A third prescription drug, called tegaserod (Zelnorm), has a complicated story. The FDA approved it in 2002 for the treatment of women with IBS (with constipation) and for men and women with chronic constipation. The drug acts by increasing the muscle contractions that move stools through your bowels. But Zelnorm was taken off the market in March 2007 after it was linked to a higher risk of heart attacks and strokes. In July 2007, the FDA allowed the drug back on the market under restricted use. But then in 2008, Novartis, the manufacturer of Zelnorm, halted the special program that made Zelnorm available and advised patients who were currently taking it to ask their doctor about alternatives. Thus, Zelnorm is not currently available to treat constipation except in rare situations considered to be life-threatening or that require hospitalization (and even then it must be obtained through a special request from a physician to the FDA).

Two other drugs to treat severe constipation are available to be administered in hospitals. They are methylnaltrexone (Relistor) and alvimopan (Entereg). Relistor, approved in 2008, is most commonly prescribed for patients who are in the advanced stages of terminal illness and may be taking an opioid drug for pain. Entereg is approved for treating constipation in people who develop it after undergoing bowel surgery.

The Choice

Your doctor's choice of treatment for your constipation will be made on a "case by case" basis. It will

depend on the type of constipation you have, its duration and severity, other medical conditions you may have and other medicines you take.

People with chronic constipation and those with IBS who have severe persistent symptoms are more likely to get a prescription medicine than people who have mild occasional constipation. Also, there are treatment preferences by age and population group. For example, parents should not give their children a laxative unless it is recommended by a doctor. And only the laxatives polyethylene glycol or lactulose should be tried, at smaller doses than those given adults. Senna and bisacodyl are not recommended for children under 6.

Pregnant and nursing women should also consult their doctor before using any laxative drug. Some laxatives can have adverse effects during pregnancy. And most are not recommended for women who are breast-feeding because they can be excreted in the milk. Better options for pregnant women are adding more fiber to their diet, taking fiber supplements, increasing their fluid intake, and exercising.

Drug-induced constipation

If your constipation is linked to a drug you are taking, your doctor is most likely to recommend increasing your intake of fiber-rich foods first. Fiber supplements are not an option since they generally don't help with drug-induced constipation. If dietary changes don't help, a laxative is usually the next step. If your constipation is triggered by an opioid drug, some data suggest polyethylene glycol is better than lactulose. As mentioned already, people who are terminally ill and may be on high doses of opioid medications to control pain may be prescribed the drug Relistor to relieve severe constipation. The drug is quite potent, however, and can trigger the opposite problem: diarrhea. So people who take this drug must be closely monitored.

Table 4. Description of Constipation Treatments

Medication Type	Brands (Examples)	Active Ingredient(s)	How They Work	Common Minor Side Effects/Cautions
Fiber supplements	Metamucil, Fiberall, Genfiber, Benefiber, Citrucel, FiberCon	guar gum, psyllium, methylcellulose, others	They absorb water into the stool to make it softer and easier to pass.	- Bloating, diarrhea, rumbling sounds, nausea, stomach cramps. - Can leave bad taste in mouth
Stool softeners	Sulfolax, Colace	docusate	These cause water and fats to mix with the stool, making it easier to move along the bowels.	Stomach ache, cramping, dehydration, or irritated throat (liquid and syrup forms)
Osmotic laxatives	Cephulac, Constulose, Kristulose, Duphalax	lactulose	They attract more water into your bowels from other parts of the body to soften the stools.	- Cramps, diarrhea, excessive or frequent bowel movements, gas, nausea. - Can leave bad taste in mouth - Pregnant and nursing women should not use.
	MiraLax, Glycolax	polyethylene glycol		
Stimulant laxatives	Dulcolax	bisacodyl	They stimulate your bowels to secrete more water and electrolytes	- Dizziness, diarrhea, nausea. - Pregnant and nursing women should not take - We advise against long-term use, but they are probably safe for acute use (i.e., 1 or 2 doses)
	Senekot, Ex-Lax	senna		
Newer Prescription Drugs	Amitiza	lubiprostone	A laxative, this drug increases intestinal fluid secretion by activating chloride channels	- Headache, nausea - Pregnant and nursing women should not take.
	Zelnorm	tegaserod maleate	Stimulates muscle motions that move stool through the bowel.	- Elevated risk of heart attack and stroke. - Sharply restricted use under FDA guidance.

Our Evaluation and *Best Buy* Pick

Unfortunately, very few studies have directly compared the various constipation drugs with each other. Even so, some useful guidance and treatment advice comes from studies that have been done.

But first, let's do some "ruling out." As discussed above, if you have chronic constipation, stool softeners probably won't help you much. Stimulant laxatives, such as senna and bisacodyl, are okay for short-term use for an occasional episode of constipation, but they also don't generally improve chronic constipation and aren't recommended for long-term use or for children under the age of 6. So we'd recommend that you rule out both stool softeners and stimulant laxatives if you are suffering from long-lasting or frequent constipation.

You can also rule out Zelnorm since it's no longer readily available, and would not be appropriate for the average constipation sufferer anyway. And again, if you decide to try a fiber supplement, we'd remind you to choose a psyllium-based one and avoid the others. This leaves a narrower band of choices if your doctor and you have decided to try a drug – namely: lactulose, polyethylene glycol, and Amitiza.

Let's discuss Amitiza first. The evidence supporting the effectiveness of this new, expensive brand-name drug is clear-cut but hardly overwhelming. For example, in some studies where Amitiza was compared to a placebo, the majority of people who got the drug did not benefit any more than those who took the placebo. All the people in the studies had fewer than three bowel movements per week before starting the study. After four weeks, 44 percent who took the drug had more than three bowel movements per week versus 24 percent who took placebo, with an average of five stools per week for people taking the drug versus 3.5 for those taking the placebo.

Amitiza's side effects were also measured. In one of the main studies the FDA used to approve the drug, for example, 62 percent of people taking Amitiza experienced at least one side effect versus 39 percent taking the placebo. The most common problem was nausea (17% who took the drug vs. 0% taking placebo)

and headache (13% vs. 6% for placebo). About 9 percent of patients had to stop taking Amitiza because of side effects. The drug has also been linked to a feeling of chest tightness and difficulty breathing.

Amitiza's use in treating IBS may be more compelling, especially since it is the only drug approved for the condition now that Zelnorm can only be obtained for rare cases that are life-threatening or that require hospitalization. The FDA's approval of Amitiza for IBS was based on two studies involving 1,154 patients. Most were women, and the majority who took the drug for 12 weeks experienced an improvement in their symptoms and more bowel movements. For that reason, the FDA only approved the drug for women. It has not been studied in children and should not be prescribed for them, or for pregnant or nursing women.

Amitiza's cost is a downside. It's an expensive new brand-name drug costing about \$300 a month (see Table 5). Our advice is to hold Amitiza in reserve and try other medicines first, even if you have been diagnosed with IBS. It's very expensive to start with and there have been no studies comparing it to more established constipation medicines. Thus, until it has been shown clearly superior to lactulose and polyethylene glycol, those drugs should be tried first. Even though neither of these medications is FDA approved for IBS, they are generally well tolerated. If you have been diagnosed with IBS and constipation and neither lactulose or polyethylene glycol help, talk to your doctor about possibly trying Amitiza.

Between lactulose and polyethylene glycol, the evidence points fairly strongly to polyethylene glycol as the first best bet, for both adults and children. In the few studies that have compared the two head-to-head in adults, people taking polyethylene glycol consistently had greater improvements in their constipation symptoms. In addition, several studies that compared constipation drugs in children found polyethylene glycol effective for up to a year with fewer side effects than milk of magnesia or lactulose. Although not conclusive, some studies have suggested kids had fewer side effects when taking polyeth-

ylene glycol as well. One study, for example, found children taking lactulose had more abdominal pain, more pain when passing a stool, and more straining than those taking polyethylene glycol.

For those reasons, and because it is an inexpensive drug, we have chosen nonprescription polyethylene glycol (MiraLax) as our *Best Buy* for treating constipation if your doctor and you have decided that you need to take a medicine. At present, MiraLax is the only version of polyethylene glycol available on store shelves. Other generic and store-brand versions will likely become available in the future. MiraLax comes in powder form to be dissolved in a liquid, usually an 8 oz. glass of water.

Note that polyethylene glycol is also available as a more expensive prescription drug. If your doctor

prescribes it, you should ask him or her why since you'll save money by just buying the nonprescription version.

Table 5 on page 13 gives you a run down of the costs of the constipation drugs. The good news is that most medicines used to treat the condition – including MiraLax – are inexpensive. Of course, the cost of these medicines depends on how often you take them. Use of all the constipation drugs varies widely. Many people only need to take one or two or a few doses a month, on an as-needed basis. Others need to take a constipation medicine on a longer-term basis, including people diagnosed with irritable bowel syndrome. Table 5 presents pricing of drugs that are more likely to be prescribed longer-term and those that we recommended for short-term use.



Table 5: Constipation Drugs – Cost Comparison*

Generic Name and Form	Brand Name(s) ¹	Number of Units Per Day ²	OTC or Rx? ³	Cost ⁴
Longer-term Use – Monthly Cost⁵				
Docusate capsule 50mg	Generic	One-Three	OTC	\$6-\$18
Docusate capsule 50mg	Colace	One-Three	OTC	\$10-\$30
Docusate capsule 100mg	Generic	One-Three	OTC	\$3-\$9
Docusate capsule 100mg	Phillips docusate	One-Three	OTC	\$6-\$18
Docusate capsule 240mg	Generic	One	OTC	\$4
Docusate capsule 240mg	Kaopectate	One	OTC	\$13
Lactulose powder 10g	Kristalose	Two-Three	Rx	\$55-\$82
Lactulose powder 20g	Kristalose	One	Rx	\$80
Lactulose solution 10g	Generic	Two-Three	Rx	\$40-\$60
Lactulose solution 10g	Enulose, Generlac, others	Two-Three	Rx	\$40-\$60
Lubiprostone capsule 8mcg	Amitiza	Two	Rx	\$220-\$294
Lubiprostone capsule 24mcg	Amitiza	Two	Rx	\$190-\$298
Polyethylene glycol powder 17g	MiraLax (OTC)	One	OTC	\$23
Polyethylene glycol powder 17g	Glycolax (Rx) or Generic	One	Rx	\$39
Short-Term Use Only – Per Episode Cost⁶				
Bisacodyl tablet 5mg	Generic	One-Three	OTC	\$1-\$2 or less
Bisacodyl tablet 5mg	Dulcolax, Ex-Lax Ultra Strength	One-Three	OTC	\$1-\$2 or less
Senna tablet 15mg	Generic	Two pills once or twice daily	OTC	\$1-\$2 or less



Table 5: Constipation Drugs – Cost Comparison* (continued)

Generic Name and Form	Brand Name(s) ¹	Number of Units Per Day ²	OTC or Rx? ³	Cost ⁴
Short-Term Use Only – Per Episode Cost⁶ (continued)				
Senna tablet 15mg	Senekot, Ex-Lax	Two pills once or twice daily	OTC	\$1-\$2 or less
Senna tablet 25mg	Generic	Two pills once or twice daily	OTC	\$1-\$2 or less
Senna tablet 25mg	Ex-Lax Maximum Strength	Two pills once or twice daily	OTC	\$1-\$2 or less
In Hospital or Special Use – Monthly Cost⁷				
Alvimopan capsule 12mg	Entereg	Two	Rx	\$950
Methylnaltrexone injection 12mg	Relistor	8-12mg every 2 days	Rx	\$569-\$1,037
Tegaserod tablet 6mg ⁸	Zelnorm	Two	Rx	Price not available

*Selected doses are listed. Also, not all brands or branded generics (of which there are many) are included.

1. "Generic" means this row lists the price for the generic version of this medicine.

2. Unit refers to pill, liquid, powdered, or injected dose, as typically recommended.

3. "OTC" means over-the-counter, indicating the drug on this row is available without a prescription. "Rx" means the drug on this row is available by prescription only.

4. Prices are from multiple sources. Among these are online pharmacies and major pharmacy chains in the Washington, DC area. Prices were obtained in December 2008. Pricing information for some prescription drugs was also derived by *Consumer Reports Best Buy Drugs* from data provided by Wolters Kluwer Health, Pharmaceutical Audit Suite.[®] This data represents nationwide averages for October 2008. Wolters Kluwer Health is not involved in our analysis or recommendations. The costs of all of these medications can vary tremendously, especially online, so we encourage you to shop around to find the best price.

5. These medicines can be taken everyday for weeks or months, but also may be taken just a few times a month for occasional constipation. We give the average monthly cost here.

6. These medicines are not recommended for long-term use. We give the average price for a single bout of constipation.

7. These are specialty medicines for severe constipation. The monthly cost is given but in practice use may be for days or a few weeks only.

8. Zelnorm is now no longer available to most patients. It can only be obtained through a special request to the FDA.

Talking With Your Doctor

It's important for you to know that the information we present here is not meant to substitute for a doctor's judgment. But we hope it will help your doctor and you arrive at a decision about which constipation drug is best for you, and which gives you the most value for your health care dollar.

Bear in mind that many people are reluctant to discuss the cost of medicines with their doctors and that studies show doctors do not routinely take price into account when prescribing medicines. Unless you bring it up, your doctors may assume that cost is not a factor for you.

Many people (including physicians) also believe that newer drugs are always or almost always better. While that's a natural assumption to make, the fact is that it's not true. Studies consistently show that many older medicines are as good as, and in some cases better than, newer medicines. Think of them as "tried and true," particularly when it comes to their safety record. Newer drugs have not yet met the test of time, and unexpected problems can and do crop up once they hit the market.

Of course, some newer prescription drugs are indeed more effective and safer. Talk with your doctor about the pluses and minuses of newer versus older medicines, including generic drugs.

Prescription medicines go "generic" when a company's patents on a drug lapse, usually after about 12 to 15 years. At that point, other companies can make and sell the drug.

Generics are almost always much less expensive than newer brand name medicines, but they are not lesser quality drugs. Indeed, most generics remain useful medicines even many years after first being marketed. That is why today about 47% of all prescriptions in the U.S. are for generics.

Another important issue to talk with your doctor about is keeping a record of the drugs you are taking. There are several reasons for this:

- First, if you see several doctors, each may not be aware of medicines the others have prescribed.
- Second, since people differ in their response to medications, it is very common for doctors to prescribe several medicines before finding one that works well or best.
- Third, many people take several prescription medications, non-prescription drugs and dietary supplements at the same time. These can interact in ways that can either reduce the benefit you get from the drug, or be dangerous.
- And fourth, the names of prescription drugs – both generic and brand – are often hard to pronounce and remember.

For all these reasons, it's important to keep a written list of all the drugs and supplements you are taking, and to periodically review this list with your doctors.

Always be sure, too, that you understand the dose of the medicine being prescribed for you and how many pills you are expected to take each day. Your doctor should tell you this information. When you fill a prescription at the pharmacy, or if you get it by mail, you may want to check to see that the dose and the number of pills per day on the pill bottle match the amounts that your doctor told you.

How We Picked the *Best Buy* Constipation Drugs

Our evaluation of medicines used to treat constipation is based on a systematic review conducted by the Oregon Health & Science University's Drug Effectiveness Review Project (DERP). Researchers screened over 500 studies and focused in on 34 that were well-conducted and looked closely at the effectiveness and/or safety of the medicines. Some of the studies also compared two or more constipation drugs.

DERP is a first-of-its-kind 13-state initiative to evaluate the comparative effectiveness and safety of hundreds of prescription drugs. A consultant to *Consumer Reports Best Buy Drugs* is also a member of the Oregon-based research team, which has no financial interest in any pharmaceutical company or product.

The DERP review of constipation drugs can be obtained at www.ohsu.edu/ohsuedu/research/policy-center/DERP/index.cfm. (DERP reports are long and technical documents written for physicians and researchers.)

In addition, we adapted material from *Consumer Reports Health*, an online subscription Web site presenting treatment options and ratings (Go to ConsumerReportsHealth.org)

Consumers Union and *Consumer Reports* is solely responsible for selecting the *Best Buy Drugs*. Our methodology is described in more detail in the Methods section at ConsumerReportsHealth.org/BestBuyDrugs.

About Us

Consumers Union, publisher of *Consumer Reports*[™] magazine, is an independent and non-profit organization whose mission since 1936 has been to provide consumers with unbiased information on goods and services and to create a fair marketplace. Consumers Union's main Web site is ConsumerUnion.org. The magazine's Web site is ConsumerReports.org. Our new health Web site is ConsumerReportsHealth.org.

Consumer Reports Best Buy Drugs[™] is a public education project administered by Consumers Union. It is partially grant funded. Principle current outside funding comes from the state Attorney General Consumer and Prescriber Education Grant Program, which is funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin.

The Engelberg Foundation provided a major grant to fund the creation of the project from 2004 to 2007. Additional initial funding came from the National Library of Medicine, part of the National Institutes of Health.

A more detailed explanation of the project is available at ConsumerReportsHealth.org.

Sharing this Report

This report should not be viewed as a substitute for a consultation with a medical or health professional. The information is meant to enhance communication with your doctor, not replace it. Use of our drug reports is also at your own risk. Consumers Union can not be liable for any loss, injury, or other damages related to your use of this report.

You should not make any changes in your prescription medicines without first consulting a physician.

We followed a rigorous editorial process to ensure that the information in this report and on the *Consumer Reports Best Buy Drugs* website is accurate and describes generally accepted clinical practices. If we find, or are alerted to, an error, we will correct this as quickly as possible. However, *Consumer Reports* and its authors, editors, publishers, licensors and any suppliers cannot be responsible for medical errors or omissions, or any consequences from the use of the information on this site.

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