

Prescription Medications for the Treatment of Obesity



U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES

WIN *Weight-control Information Network*

Obesity is a chronic disease that affects many people and often requires long-term treatment to promote and sustain weight loss. As in other chronic conditions, such as diabetes or high blood pressure, long-term use of prescription medications may be appropriate for some people.

*Prescription weight-loss medications should be used only by patients who are at increased medical risk because of their weight. They should not be used for “cosmetic” weight loss. Prescription weight-loss drugs are approved only for those with a body mass index (BMI) of 30 and above, or 27 and above if they have obesity-related conditions, such as high blood pressure, dyslipidemia (abnormal amounts of fat in the blood), or type 2 diabetes. BMI is a measure of weight in relation to height. A BMI of 18.5 to 24.9 is considered healthy. (See WIN’s brochure *Weight and Waist Measurement: Tools for Adults* for more information.)*

Although most side effects of prescription medications for obesity are mild, serious complications have been reported. Also, there are few studies lasting more than 2 years evaluating the safety or effectiveness of weight-loss medications. Weight-loss medications should always be combined with a program of healthy eating and regular physical activity.

The information in this fact sheet may help you decide if and what kind of weight-loss medication may help you in your efforts to reach and stay at a healthy weight. It does not replace medical advice from your doctor.

Medications That Promote Weight Loss

- **Appetite suppressants.** Most available weight-loss medications approved by the Food and Drug Administration (FDA) are appetite-suppressant medications. Appetite-suppressant medica-

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Until more information on their safety or effectiveness is available, using combinations of medications for weight loss is not recommended, except as part of a research study.

tions promote weight loss by decreasing appetite or increasing the feeling of being full. These medications make you feel less hungry by increasing one or more brain chemicals that affect mood and appetite. Phentermine and sibutramine are the most commonly prescribed appetite-suppressants in the U.S.

NOTE: Amphetamines are a type of appetite suppressant. However, amphetamines are not recommended for use in the treatment of obesity due to their strong potential for abuse and dependence.

- **Lipase inhibitors.** One drug works in a different way. Orlistat works by reducing the body's ability to absorb dietary fat by about one third. It does this by blocking the enzyme lipase, which is responsible for breaking down dietary fat. When fat is not broken down, the body cannot absorb it, so fewer calories are taken in.
- **Other medications (not FDA-approved for the treatment of obesity).**

Drugs to treat depression. Some antidepressant medications have been studied as appetite-suppressant medications. While these medications are FDA-approved for the treatment of depression, their use in weight loss is an "off-label" use (see box). Studies of these medications generally have found that patients lose modest amounts of weight for up to 6 months, and tend to regain weight while they are still on the drug. One exception is bupropion. In one study, patients taking bupropion maintained weight loss for up to 1 year.

What is "off-label" use?

Although the FDA regulates how a medication can be advertised or promoted by the manufacturer, these regulations do not restrict a doctor's ability to prescribe the medication for different conditions, in different doses, or for different lengths of time. The practice of prescribing medication for periods of time or for conditions not FDA-approved is known as "off-label" use. While such use often occurs in the treatment of many conditions, *you should feel comfortable about asking your doctor if he or she is using a medication or combination of medications in a manner that is not approved by the FDA*

Table 1. FDA-Approved Prescription Weight-loss Medications

Generic Name	Trade Name(s)	Drug Type	FDA Approval Date
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Drugs to treat seizures. Two medications used to treat seizures, topiramate and zonisamide, have been shown to cause weight loss. Whether these drugs will be useful in treating obesity is being studied.

Drugs to treat diabetes. The diabetes medication metformin may promote small amounts of weight loss in people with obesity and type 2 diabetes. How this medication promotes weight loss is not clear, although research has shown reduced hunger and food intake in people taking the drug.

Drug combinations. The combined drug treatment using fenfluramine and phentermine (“fen/phen”) is no longer available due to the withdrawal of fenfluramine from the market after some patients experienced serious heart and lung disorders. (See page 5 for more information.) Little information is available about the safety or effectiveness of other drug combinations for weight loss, including fluoxetine/phentermine, phendimetrazine/phentermine, orlistat/sibutramine, herbal combinations, or others. *Until more information on their safety or effectiveness is available, using combinations of medications for weight loss is not recommended, except as part of a research study.*

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Because weight-loss medications are used to treat a condition that affects millions of people, many of whom are basically healthy, the possibility that side effects may outweigh benefits is of great concern.

Drugs in development. Many medications are being tested as potential treatments for obesity. Two are being studied with patients in clinical trials. Rimonabant affects brain chemicals and ciliary neurotrophic factor affects hormones to control appetite. Currently, these medications are only available in clinical trials. Clinical trials are research studies with human volunteers so that specific health questions can be answered.

Potential Benefits of Medication Treatment

People respond differently to weight-loss medications, and some people experience more weight loss than others. Weight-loss medications lead to an average weight loss of 5 to 22 pounds more than what you might lose with non-drug obesity treatments. Some patients using medication lose more than 10 percent of their starting body weight. Maximum weight loss usually occurs within 6 months of starting medication treatment. Weight then tends to level off or increase during the remainder of treatment.

Over the short term, weight loss in individuals who are obese may reduce a number of health risks. Studies have found that weight loss with some medications improves blood pressure, blood cholesterol, triglycerides (fats), and insulin resistance (the body's inability to use blood sugar). New research suggests that long-term use of weight-loss medications may help individuals keep off the weight they have lost. However, more studies are needed to determine the long-term effects of weight-loss medications on weight and health.

Potential Risks and Concerns

When considering long-term weight-loss medication treatment for obesity, you should consider the following areas of concern and potential risks.

- **Potential for abuse or dependence.** Currently, all prescription medications to treat obesity except orlistat are controlled substances, meaning doctors need to follow certain restrictions when prescribing them. Although abuse and dependence are not common with non-amphetamine appetite-suppressant medications, doctors should be cautious when they prescribe these medications for patients with a history of alcohol or other drug abuse.
- **Development of tolerance.** Most studies of weight-loss medications show that a patient's weight tends to level off after 6 months while still on medication. Although some patients and doctors may be concerned that this shows tolerance to the medications, the

leveling off may mean that the medication has reached its limit of effectiveness. Based on the currently available studies, it is not clear if weight gain with continuing treatment is due to drug tolerance. It is clear, however, that weight gain would be much faster if the patient stopped taking the drug.

- **Reluctance to view obesity as a chronic disease.** Obesity often is viewed as the result of a lack of willpower, weakness, or a lifestyle “choice”—the choice to overeat and underexercise. Such social views on obesity should not prevent patients from seeking medical treatment to prevent health risks that can cause serious illness and death. Weight-loss medications, however, are not “magic bullets” or a one-shot fix for this chronic disease. They should be combined with a healthy eating plan and increased physical activity.
- **Side effects.** Because weight-loss medications are used to treat a condition that affects millions of people, many of whom are basically healthy, the possibility that side effects may outweigh benefits is of great concern. Most side effects of these medications are mild and usually improve with continued treatment. Rarely, serious and even fatal outcomes have been reported. Side effects of medications are explained below.

Orlistat. Some side effects of orlistat include cramping, intestinal discomfort, passing gas, diarrhea, and leakage of oily stool. These side effects are generally mild and temporary, but may be worsened by eating foods that are high in fat. Also, because orlistat reduces the absorption of some vitamins, patients should take a multivitamin at least 2 hours before or after taking orlistat.

Sibutramine. The main side effects of sibutramine are increases in blood pressure and heart rate, which are usually small but may be of concern in some patients. Other side effects include headache, dry mouth, constipation, and insomnia. People with poorly controlled high blood pressure, heart disease, irregular heartbeat, or history of stroke should not take sibutramine, and all patients taking the medication should have their blood pressure monitored on a regular basis.

Other appetite suppressants. Phentermine, phendimetrazine, and diethylpropion may cause symptoms of sleeplessness, nervousness, and euphoria (feeling of well-being). People with heart disease, high blood pressure, an overactive thyroid gland, or glaucoma should not use these drugs.

Two appetite-suppressant medications, fenfluramine and dexfenfluramine, were withdrawn from the market in 1997. These drugs, used alone and in combination with phentermine

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(“fen/phen”) were linked to the development of valvular heart disease and primary pulmonary hypertension (PPH), a rare but potentially fatal disorder that affects the blood vessels in the lungs. There have been only a few case reports of PPH in patients taking phentermine alone, but the possibility that phentermine use is associated with PPH cannot be ruled out.

Commonly Asked Questions About Weight-Loss Medications

Q: Can medications replace physical activity or changes in eating habits as a way to lose weight?

A: No. Studies show that weight-loss medications work best when combined with a weight-control program that helps you improve your eating and physical activity habits. Ask your doctor about ways you can improve your eating plan and become more physically active.

Q: What medical conditions or medications might influence my decision to take a weight-loss drug?

A: Let your doctor know if you have any of the following medical conditions, which may affect which weight-loss drugs you can take, if any:

- Pregnancy or breast-feeding
- History of drug or alcohol abuse
- History of anorexia or bulimia
- History of depression or manic depressive disorder
- Use of monoamine oxidase (MAO) inhibitors or antidepressant medications
- Migraine headaches requiring medication
- Glaucoma
- Diabetes
- Heart disease or heart condition, such as an irregular heart beat
- High blood pressure
- Plan to have surgery that requires general anesthesia.

Q: How long will I need to take weight-loss medications to treat obesity?

A: The answer depends upon whether the medication helps you to lose and maintain weight and whether you have any side effects. Because obesity is a chronic disease, any treatment, whether drug or non-drug, may need to be continued for years, and perhaps a lifetime, to improve health and maintain a healthy weight. However, like many other types of drugs, there is still little information on how safe and effective weight-loss medications are for many years of use. At least one study has shown that intermittent use (one month on medication and one month off medication) may help some people lose and maintain weight, but more research is needed.

Q: Will I regain some weight after I stop taking weight-loss medications?

A: Probably. Most studies show that the majority of patients who stop taking weight-loss medications regain the weight they lost. Maintaining healthy eating and physical activity habits may help you regain less weight.

Q: Can children or teens use weight-loss medications?

A: Orlistat is currently approved for use in teens age 12 or above. Other weight-loss medications are not approved for use in children under the age of 16, although studies in children and teens are ongoing.

Q: Will insurance cover the cost of weight-loss medication?

A: Many insurance companies currently will not pay for weight-loss prescriptions, but this is changing as insurers begin to recognize obesity as a chronic disease. Contact your insurance company to find out if prescription weight-loss medication is covered under your plan. The cost of one month of a prescription can cost about 60 dollars a month to more than twice this amount. Ask a staff member at your pharmacy the cost of a 1-month supply of the medication you are considering taking.



Most patients should not expect to reach an “ideal” body weight using currently available medications. However, even a modest weight loss of 5 to 10 percent of your starting body weight can improve your health. Together, you and your doctor can make an informed choice as to whether medication can be a useful part of your weight-control program.

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Weight-control Information Network

1 WIN WAY

BETHESDA

MD 20892-3665

Phone: (202) 828-1025

Toll-free number:

1-877-946-4627

FAX: (202) 828-1028

Email:

WIN@info.niddk.nih.gov

Internet:

www.win.niddk.nih.gov

The Weight-control Information Network (WIN) is a national information service of the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health, which is the Federal Government's lead agency responsible for biomedical research on nutrition and obesity. Authorized by Congress (Public Law 103-43), WIN provides the general public, health professionals, the media, and Congress with up-to-date, science-based health information on weight control, obesity, physical activity, and related nutritional issues.

Publications produced by WIN are reviewed by both NIDDK scientists and outside experts. This fact sheet was also reviewed by Myrlene Staten, Ph.D., Senior Advisor, Diabetes Translational Research; Division of Diabetes, Endocrinology, and Metabolic Diseases; NIDDK.



National Institute of Diabetes and
Digestive and Kidney Diseases

NIH Publication No. 04-4191
November 2004

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