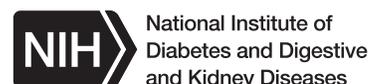


Prescription Medications for the Treatment of Obesity

U.S. Department of Health and Human Services



WIN *Weight-control Information Network*

Introduction

Obesity is a chronic condition that affects many people. If you are struggling with excess weight, you may find that a healthy eating plan and regular physical activity help you lose weight and maintain weight loss over the long term. But if these lifestyle changes are not enough, prescription medications for obesity treatment may be a helpful part of your weight-control program.

When combined with healthy eating and regular physical activity, prescription obesity drugs may help some people lose weight and improve their health. But these drugs have side effects and may not work for everyone.

This fact sheet will tell you more about the prescription medications that may be used to treat obesity. Talk to your health care provider if you think these medications may help you.

How do these drugs work?

Prescription drugs for the treatment of obesity work in different ways. For example, some drugs may help you feel less hungry or feel full sooner. Others may make it hard for your body to absorb fat from the foods you eat.

These medicines are meant to help people who may be having health problems related to excess weight. See the box “Who may use obesity medications?” for more information. Your doctor will also consider the drugs’ side effects, your family’s medical history, and your current health issues and medicines.

Who may use obesity medications?

Health care providers often use the body mass index (BMI) to help decide who may benefit from weight-loss drugs. BMI estimates overweight and obesity based on your height in relation to your weight. Your doctor may prescribe you a medication to treat your obesity if you are an adult with

- a BMI of 30 or greater OR
- a BMI of 27 or greater and you have obesity-related medical problems, such as high blood pressure, type 2 diabetes, or high cholesterol

To check your BMI, see the Resources section for a link to the Online BMI Calculator. Before using a weight-loss drug, you should first try to lose weight by changing your eating and physical activity habits.

What are the benefits?

When combined with changes to eating and physical activity, prescription drugs may help some people lose weight (usually less than 10 percent of their body weight). Results vary by drug and by person. Losing weight may help improve your health by lowering blood sugar, blood pressure, and triglycerides (other fats in the blood). Weight loss of 5 to 10 percent can

also improve inflammation profiles and improve how patients feel and their mobility.

Most weight loss takes place in the first 6 months of starting the medicine. After that time, you may lose weight more slowly or begin to regain weight.

What are the concerns?

Because obesity drugs are used to treat a condition that affects millions of people, the chance that side effects may outweigh benefits is of great concern. This is why one should never take a weight loss medicine only for cosmetic benefit. In the past, some drugs for obesity treatment were linked to serious health problems. An example is sibutramine (sold as Meridia), recalled in 2010 because of concerns related to heart disease and stroke.

Possible side effects vary by drug and how it acts on your body. See the next section of this fact sheet for the specific side effects of each weight-loss drug. Most side effects are mild and usually improve if you continue to use the drug.

What drugs are available?

The Food and Drug Administration (FDA) is the Government agency that reviews and approves prescription drugs for treating specific health problems. Table 1 (“Prescription Drugs Approved for Obesity Treatment”) lists the prescription drugs approved by the FDA for weight control. Three of these drugs—orlistat, lorcaserin, and phentermine-

topiramate—are approved for long-term use. This means that you may take them for several months at a time, even years.

Other weight-loss drugs that curb appetite are only approved by the FDA for short-term use (a few weeks), but some doctors prescribe them for longer periods (see the box “What is ‘off-label’ use?”). These medications are also controlled substances because of their potential for abuse. Most weight-loss drugs are only approved for use by adults. Orlistat is approved for children ages 12 and older. **Weight loss medications should never be used during pregnancy, and weight loss is not advised during pregnancy.** Women who are thinking about becoming pregnant should avoid some of these drugs, as they may harm an unborn baby. The drugs outlined in Table 1 are described in more detail in the sections that follow.

Orlistat (Xenical and Alli)

The drug orlistat, sold under the brand name Xenical (pronounced ZEN-i-cal), has been available since 1999. It is approved for use by adults and children ages 12 and older.

The over-the-counter version of orlistat is sold under the brand name Alli. The two drugs contain different amounts of orlistat. Xenical contains 120 mg, while Alli contains 60 mg. Alli is not approved for use by children.

Orlistat will stop about one-third of the fat from the food you eat from being digested. It does so by blocking the enzyme lipase, which breaks down fat. When fat is not broken down, the body cannot absorb it, so fewer calories are taken in. After 1 or 2 years of taking orlistat, patients may lose about 5 to 7 pounds.

Side effects. Common side effects of orlistat include stomach pain, gas, diarrhea, and leakage of oily stool. These side effects are generally mild and temporary, but may be worse when you eat high-fat foods. You should eat a low-fat diet (less than 30 percent of calories from fat) before starting to take this drug. Because orlistat prevents some vitamins from being absorbed, **you should take a multivitamin while using orlistat.**



TABLE 1. Prescription Drugs Approved for Obesity Treatment

Weight-loss drug	Approved for	How it works	Common side effects
Orlistat Sold as Xenical by prescription Over-the-counter version sold as Alli	Xenical: adults and children ages 12 and older Alli: adults only	Blocks some of the fat that you eat, keeping it from being absorbed by your body.	Stomach pain, gas, diarrhea, and leakage of oily stools. Note: Rare cases of severe liver injury reported. Should not be taken with cyclosporine.
Lorcaserin Sold as Belviq	Adults	Acts on the serotonin receptors in the brain. This may help you eat less and feel full after eating smaller amounts of food.	Headaches, dizziness, feeling tired, nausea, dry mouth, cough, and constipation. Should not be taken with selective serotonin reuptake inhibitors (SSRIs) and monoamine oxidase inhibitor (MAOI) medications.
Phentermine-topiramate Sold as Qsymia	Adults	A mix of two drugs: phentermine (suppresses your appetite and curbs your desire to eat) and topiramate (used to treat seizures or migraine headaches). May make you feel full and make foods taste less appealing.	Tingling of hands and feet, dizziness, taste alterations (particularly with carbonated beverages), trouble sleeping, constipation, and dry mouth. Note: Sold only through certified pharmacies. MAY LEAD TO BIRTH DEFECTS. DO NOT TAKE QSYMIA IF YOU ARE PREGNANT OR PLANNING A PREGNANCY.
Other appetite suppressant drugs (drugs that curb your desire to eat), which include <ul style="list-style-type: none"> • phentermine • benzphetamine • diethylpropion • phendimetrazine Sold under many names	Adults	Increase chemicals in the brain that affect appetite. Make you feel that you are not hungry or that you are full. Note: Only FDA approved for a short period of time (up to 12 weeks).	Dry mouth, difficulty sleeping, dizziness, headache, feeling nervous, feeling restless, upset stomach, diarrhea, and constipation.

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Rare cases of severe liver injury have been reported. Stop using the drug and see your health care provider immediately if you develop symptoms of liver problems. These symptoms may include dark urine, itching, light-colored stools, loss of appetite, or yellow eyes or skin. Orlistat should not be taken with cyclosporine.

Lorcaserin (Belviq)

Belviq (pronounced BEL-VEEK), works by affecting chemicals in your brain that help decrease your appetite and make you feel full, so you eat less.

In studies done as part of the drug approval process, almost half (47 percent) of patients taking Belviq lost at least 5 percent of their initial body weight at 1 year. If you do not lose 5 percent of your weight within 12 weeks of being on the drug, it is unlikely that the medicine will work for you, and it should be stopped.

Side effects. Common side effects of Belviq include headaches, dizziness, feeling tired, nausea, dry mouth, cough, and constipation. A rare but serious side effect is serotonin syndrome (high fever, muscle rigidity, and confusion), which can occur if the drug is taken along with SSRI antidepressants or MAOI medications. Belviq, as with all weight-loss agents, should not be taken if you are pregnant or planning to become pregnant.

Phentermine-topiramate (Qsymia)

In July 2012, the FDA approved the drug combination phentermine and topiramate, sold as Qsymia (pronounced kyoo-sim-EE-uh) to treat obesity in adults. Qsymia combines two FDA-approved drugs:

- phentermine, a medicine approved to suppress appetite.
- topiramate, a medicine approved to control seizures. It may also be used to prevent migraine headaches. It is in an extended-release form in Qsymia.

Although phentermine when used as a single agent is approved for only a few weeks, the combination

has been studied for 2 years and found to be safe for use. Additionally, the doses used in Qsymia are much lower than the usual doses of phentermine and topiramate when prescribed separately.

Qsymia is available in three doses: a starting dose, a recommended dose, and a higher dose. After 1 year of treatment with Qsymia, 62 percent of patients who were prescribed the recommended dose lost at least 5 percent of their weight. If after 12 weeks on the higher dose, you do not lose at least 5 percent of your body weight, it is unlikely that the drug will work for you.

Side effects. Common side effects include tingling of hands and feet, dizziness, taste alterations (particularly with carbonated beverages), trouble sleeping, constipation, and dry mouth. Serious but rare side effects include allergic reactions (such as rash, hives, difficulty breathing), thoughts of suicide, memory problems, mood problems (such as anxiety, depression, panic attacks), and changes to your vision. Rare side effects associated with topiramate include kidney stones and acute glaucoma. **Qsymia must not be used during pregnancy because it may cause harm to the baby.** People with an overactive thyroid gland, glaucoma, or who have recently taken certain antidepressant drugs known as MAOIs should not use Qsymia, although the drug was studied in patients taking SSRI and other antidepressants without adverse events.

Other Appetite Suppressants

These drugs promote weight loss by increasing one or more brain chemicals that affect appetite. You may feel less hungry or feel full sooner when taking these drugs. They are FDA approved only for a short period of time (up to 12 weeks). Some doctors may prescribe them for longer periods of time (see the box “What is ‘off-label’ use?”).

Several appetite suppressants may be used to promote weight loss in adults. They include

- phentermine (sold as Adipex-P, Oby-Cap, Suprenza, T-Diet, Zantryl)
- benzphetamine (sold as Didrex)

- diethylpropion (sold as Tenuate, Tenuate Dospan)
- phendimetrazine (sold as Adipost, Bontril PDM, Bontril Slow Release, Melfiat)

Among these types of drugs, phentermine is the one used most often in the United States.

Side effects. Common side effects of appetite suppressants include dry mouth, difficulty sleeping, dizziness, headache, feeling nervous, feeling restless, upset stomach, and diarrhea or constipation. Severe side effects may include chest pain, fainting, fast heartbeat, shortness of breath, confusion, and swelling in your ankles or feet. People with heart disease, high blood pressure, an overactive thyroid gland, or glaucoma should not use these drugs. These medications are controlled substances because of their potential for abuse.

What other prescription drugs do doctors use “off-label” for obesity treatment?

Some medicines that have been approved to treat other health problems may also be used for weight loss. Using a medicine for a different purpose from that for which it was approved, in a different population, or for a longer period of time is called using it in an “off-label” way (see box “What is ‘off-label’ use?”).

Other prescription drugs some doctors prescribe off label to promote weight loss include

- bupropion, a drug used to treat depression
- metformin, a drug used to treat type 2 diabetes

The side effects of these medications and the population for whom they might be appropriate vary. Drugs prescribed off label also have not met the rigorous standards of FDA approval as an obesity treatment.

What is “off-label” use?

Health care providers have some leeway in how they may prescribe drugs approved by the FDA. For example, in treating obesity, health care providers may

- prescribe a drug approved for treating another medical problem
- prescribe two or more drugs at the same time
- prescribe a drug for a longer period of time than approved by the FDA

These types of off-label uses are common in treating many health problems. You should feel comfortable asking your doctor if he or she is using a medicine in an off-label way.

What other drugs may be approved and available in the future?

Several new drugs and drug combinations are currently being studied in animals as well as in clinical trials in humans. Research is ongoing to identify more safe and effective medications to help patients with obesity lose weight and maintain a healthy weight for a long time.

Future drugs may use new strategies, such as these:

- combining drugs that affect appetite and those that affect addiction (or craving)
- stimulating gut hormones that reduce appetite
- shrinking the blood vessels that feed fat cells in the body, thereby preventing them from growing
- targeting genes that affect body weight
- using bacteria in the gut to control weight

How can I improve my physical activity levels?

Federal guidelines recommend 300 minutes (5 hours) or more each week of moderate or vigorous aerobic activity for people trying to lose more than 5 percent of their weight or to maintain weight after meeting weight-loss goals. Aerobic activity uses your large muscle groups (chest, legs, and back) to increase your heart rate. This activity may cause you to breathe harder. Examples of moderate aerobic activity are these:

- bicycling (with a helmet)
- brisk jogging or walking
- dancing
- playing basketball or soccer
- swimming



Common Questions and Answers

- Q:** Can drugs replace physical activity or changes in eating habits as a way to lose weight?
- A:** No. Studies show that weight-loss drugs work best when used 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 add more physical activity to your life.
- Q:** How do I decide which obesity medication is right for me?
- A:** Choosing a medication to treat obesity is a decision between you and your health care provider. You will consider the drug's side effects, your family's medical history, and your current health issues and medicines.
- Q:** How long will I need to take weight-loss drugs?
- A:** The answer depends upon whether the drug helps you to lose and maintain weight and whether you have any side effects. Because obesity is a chronic condition, changes to diet and physical activity may need to be continued for years, perhaps a lifetime, to improve health and maintain a healthy weight.
- Q:** Will I regain some weight after I stop taking weight-loss drugs?
- A:** Probably. Most people who stop taking obesity medications regain the weight they lost. Maintaining healthy eating habits and increasing physical activity may help you regain less weight or keep it off. See the callout box on physical activity for information on recommended types and amounts of physical activity for people trying to lose weight. For tips on healthy eating, check out the Weight-control Information

Network (WIN) publication *Just Enough for You: About Food Portions*, listed in the Resources section at the end of this fact sheet.

Q: Can children or teens use obesity medications?

A: Most weight-loss drugs are approved only for use in adults. Prescription orlistat (sold as Xenical) is approved for use in teens ages 12 or older.

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

A: Some, but not all, insurers cover medications for the treatment of obesity. Contact your insurance provider to find out if these medicines are covered under your plan.

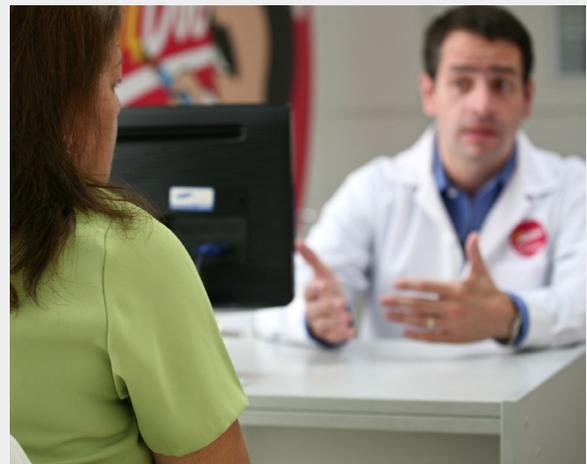
Research

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports a broad range of basic and clinical obesity research. More information about obesity research is available at <http://www.obesityresearch.nih.gov>.

Clinical trials are research studies involving people. Clinical trials look at safe and effective new ways to prevent, detect, or treat disease. Researchers also use clinical trials to look at other aspects of care, such as improving the quality of life for people with chronic illnesses. To learn more about clinical trials, why they matter, and how to participate, visit the NIH Clinical Research Trials and You website at <http://www.nih.gov/health/clinicaltrials>. For information about current studies, visit <http://www.ClinicalTrials.gov>.

Dos and Don'ts of Using Weight-loss Drugs

- DO follow your primary care provider's advice about weight-loss drugs.
- DON'T obtain medications over the Internet.
- DO use weight-loss medications to reinforce your lifestyle change program.
- DON'T think the drugs will work by themselves to replace a diet and physical activity program.
- DO know the side effect profiles and precautions in using any medication.
- DON'T continue medications if you are not losing weight after a trial (usually 12 weeks).
- DO discuss other medications you are taking with your doctor when considering weight-loss medications.
- DON'T take weight-loss medications during pregnancy.



Resources

Additional Reading from the Weight-control Information Network

The following publications are available online at <http://www.win.niddk.nih.gov/publications> and also by calling WIN toll-free at 1-877-946-4627:

- **Choosing a Safe and Successful Weight-loss Program** offers guidelines to help readers talk with their health care providers about weight-loss programs.
- **Just Enough for You: About Food Portions** explains the difference between a portion and a serving, as well as offers tips to help readers eat healthy portions.
- **Physical Activity and Weight Control** explains how regular physical activity may help readers reach and keep a healthy weight.
- **Understanding Adult Overweight and Obesity** provides basic information about obesity: What is it? How is it measured? What causes it? What are the health risks? What can you do about it?

Additional Resources

- **Food and Drug Administration.** Provides information about drug approvals, prescription drugs, over-the-counter drugs, drug safety, clinical trials, public health alerts, and other topics. <http://www.fda.gov>
- **Mayo Clinic.** Offers information about drugs and supplements. <http://www.mayoclinic.com/health/drug-information/DrugHerbIndex>
- **National Center for Complementary and Alternative Medicine.** Provides information on options other than prescription drugs, such as herbal supplements and acupuncture. <http://www.nccam.nih.gov>
- **National Library of Medicine Drug Information Portal.** Offers information about specific drugs. <http://druginfo.nlm.nih.gov/drugportal/drugportal.jsp>
- **Online BMI Calculator for Adults.** <http://www.nhlbi.nih.gov/guidelines/obesity/BMI/bmicalc.htm>

Inclusion of resources is for information only and does not imply endorsement by NIDDK or WIN.

Medications Disclaimer

This publication may contain information about medications and, when taken as prescribed, the conditions they treat. When prepared, this publication included the most current information available. For updates or for questions about any medications, contact the U.S. Food and Drug Administration toll-free at 1-888-INFO-FDA (1-888-463-6332) or visit <http://www.fda.gov>. Consult your health care provider for more information.

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The Weight-control Information Network (WIN) is a national information service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health (NIH). WIN provides the general public, health professionals, and the media with science-based, up-to-date, culturally relevant materials and tips. Topics include healthy eating, barriers to physical activity, portion control, and eating and physical activity myths.

Publications produced by WIN are carefully reviewed by both NIDDK scientists and outside experts. This fact sheet was also reviewed by Donna H. Ryan, M.D., F.A.C.P., Pennington Biomedical Research Center.

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This publication is also available at <http://www.win.niddk.nih.gov>.

You may also find additional information about this topic by visiting MedlinePlus at <http://www.medlineplus.gov>.

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