

Dear Doctor +

Can losing weight too fast hurt me?



Answer Provided by
Deborah Horn, DO, MPH, MFOMA

I am committed!
I am starting today!
I want it off by TOMORROW!

Almost everyone who struggles with their weight has had this mental conversation. It may have taken years or decades of abnormal physiology and struggling with good choices to put weight on, but once we are committed to change, we want it off now! Similar to the fast-paced technological world we live in today, we want the scale to move at lightning speed. But does rapid weight-loss work? And is it safe?



Please note: Before starting any weight-loss program, please consult with your primary care physician.

What Doesn't Work...

Many promises of rapid weight-loss are a result of mass marketing and commercial approaches – the ones you see on infomercials at 2 am or read about as the latest Hollywood “secret.” Do any of these sound familiar?

“Drop a dress size in 7 days.”

“Lose weight fast – no exercise required.”

“Boost your metabolism!”

These diets make unproven promises. They often claim to increase your ability to burn fat, simply block the fat you eat, “rev up” your metabolism, or provide a miracle pill composed of “newly-discovered compounds.” Components of these diets often include gimmicks and unproven approaches such as:

- Starvation diets
- Over the counter (OTC) pills and supplements
- Cleanses and detoxification diets
- Colonics and enemas
- Non-FDA approved injections such as HCG

While you might lose weight with these gimmicks initially, this is typically due to a severely decreased caloric intake. Most of these diets promise weight-loss without the need for physical activity – and frankly, on such a low-calorie intake, you don't feel well enough to exercise anyway. Without medical monitoring from a healthcare professional, these options can lead to serious health risks. Additionally, most of these rapid weight-loss approaches are not sustainable – and once stopped, the weight will most likely come right back.

Dear Doctor continued on page 16

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What DOES Work...

There are two medically monitored and proven options for rapid weight-loss:

- Very low calorie diets, “VLCD’s”
- Bariatric surgery

Both of these options are very different from the gimmicks on page 14 in that they have proven results, known side effects, and they allow you to work alongside your healthcare provider to optimize your response.

Option 1: VLCD’s

Medically-monitored VLCD’s are typically diets of less than 800 calories. The plan is often built around a nutritionally complete protein-based meal replacement in the form of a shake, although it can be done with regular food as well. This rapid weight-loss approach focuses on high intake of protein and decreased intake of carbohydrates. Whether protein is built into a shake or taken separately, these diets require an adequate intake of vitamins, minerals, electrolytes and fatty acids. VLCD’s have been shown to demonstrate not just faster weight-loss, but also greater weight-loss at one year than dietary interventions which did not include a VLCD component.

Option 2: Bariatric Surgery

Bariatric surgery can include gastric bypass, gastric sleeve and the gastric band. There are also intermediary procedures available such as the gastric balloon. All of these are currently FDA-approved and create rapid weight-loss in most patients. The rate and total amount of weight-loss can vary widely from person to person.

So, there are some proven and some unproven options for rapid weight-loss. Let’s come back to our initial question. Can losing weight too fast hurt me?

Yes. There are potential negative effects of rapid weight-loss. For this reason and many others, it is recommended that you team up with an obesity medicine specialist, a bariatric surgeon or other experienced healthcare provider with expertise in the treatment of overweight and obesity. Together, you can reduce the risks and optimize the benefits if you choose a rapid weight-loss strategy.

Most Common Rapid Weight-loss Risks:

- **Hypoglycemia** – This is better known as low blood sugar. If you have diabetes and you are on diabetes medication, your dose of medication can quickly become too high during rapid weight-loss.

What can you do?

Medications like insulin and a group of medications called oral sulfonylureas are particularly important to follow under medical supervision. Diabetes medications often need to be decreased before starting the intervention – or at a minimum, quickly decreased in the very beginning and throughout your weight-loss journey.



- **Gallstones** – The risk of gallstone formation and acute gallbladder disease requiring gallbladder removal is greater with rapid weight-loss. New gallstones were found in 25-35 percent of individuals on a rapid weight-loss plan. This risk was highest when the rate of weight-loss exceeded approximately 1.5 percent of body weight per week. For example, in a 300-pound individual, this risk would be increased when more than 4.5 pounds per week are lost. Symptoms include right upper abdominal pain – particularly after a meal.

What can you do?

Discuss this with your doctor. If you still have your gallbladder and you have a history of gallstones and/or acute gallbladder disease, you may consider a medication called ursodeoxycholic acid. Studies show that this medication, when used during rapid weight-loss, can decrease gallstone formation from 28-32 percent of individuals to only 2-3 percent of individuals.



- **Hypotension** – This is better known as low blood pressure. If you are on medication to treat your blood pressure, you can be at risk for dizziness, lightheadedness and potentially falling/injury if your blood pressure becomes too low.

What can you do?

Blood pressure medications often need to be adjusted at the beginning or very early on in a rapid weight-loss plan in order to avoid these risks. Your doctor can help you manage these changes appropriately.



- **Muscle Loss** – Strong, lean skeletal muscle is one of the major components of metabolism. Muscle is at higher risk of loss during rapid weight-loss attempts when compared to more conservative rates of weight-loss. When we lose weight, individuals typically lose 30-40 percent of their weight from this strong lean muscle. You won't have any symptoms to identify the problem.

What can you do?

Make sure you are working with your doctor to monitor your muscle mass as you are losing weight. This is done by frequently measuring your body composition. Getting adequate protein in your diet and stimulating muscles with physical activity may help decrease this loss of lean strong muscle. Scientists are still determining how this may affect your metabolism long-term, and it is likely to be different in different people.



- **Dehydration** – Decreased fluid intake, decreased salt intake and decreased carbohydrate intake can all lead to decreased total body water. Lightheadedness and/or dizziness are the most common symptoms.

What can you do?

Drink plenty of fluids. If you are on medication for high blood pressure, this may need to be adjusted sooner on a rapid weight-loss plan as some of these medications work by decreasing your total body fluid. With a change in nutrition and weight, you may need to consider a lower dose or the discontinuation of these medications.



- **Electrolyte Imbalances** – This includes changes in magnesium, calcium, potassium and others. Symptoms can vary.

What can you do?

Any very low-calorie diet or bariatric surgery intervention should include regularly scheduled labs to check these electrolytes and provide supplementation as needed. Your obesity medicine specialist or bariatric surgeon can help you monitor these at appropriate intervals.



Dear Doctor continued on page 21

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Ask your healthcare professional about BELVIQ®

What is BELVIQ®?

BELVIQ is an FDA-approved prescription weight-loss medication that, when used with diet and exercise, can help some overweight (Body Mass Index [BMI] ≥ 27 kg/m²) adults with a weight-related medical problem, or adults living with obesity (BMI ≥ 30 kg/m²), lose weight and keep it off.

It is not known if BELVIQ when taken with other prescription, over-the-counter, or herbal weight-loss products is safe and effective. It is not known if BELVIQ changes your risk of heart problems, stroke, or death due to heart problems or stroke.

Important Safety Information

- **Pregnancy:** Do not take BELVIQ if you are pregnant or planning to become pregnant, as weight loss offers no potential benefit during pregnancy and BELVIQ may harm your unborn baby.
- **Hypersensitivity Reactions:** Do not take if you are allergic to either of these medicines or any of their ingredients.
- **Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions:** Before using BELVIQ, tell your doctor about all the medicines you take, especially medicines that treat depression, migraines, mental problems, or the common cold. These medicines may cause serious or life-threatening side effects if taken with BELVIQ. Call your doctor right away if you experience agitation, hallucinations, confusion, or other changes in mental status; coordination problems; uncontrolled muscle spasms; muscle twitching; restlessness; racing or fast heartbeat; high or low blood pressure; sweating; fever; nausea; vomiting; diarrhea; or stiff muscles.
- **Valvular heart disease:** Some people taking medicines like BELVIQ have had heart valve problems. Call your doctor right away if you experience trouble breathing; swelling of the arms, legs, ankles, or feet; dizziness, fatigue, or weakness that will not go away; or fast or irregular heartbeat. Before taking BELVIQ, tell your doctor if you have or have had heart problems.
- **Changes in attention or memory:** BELVIQ may slow your thinking. You should not drive a car or operate heavy equipment until you know how BELVIQ affects you.
- **Mental problems:** Taking too much BELVIQ may cause hallucinations, a feeling of being high or in a very good mood, or feelings of standing outside your body.
- **Depression or thoughts of suicide:** Call your doctor right away if you notice any mental changes, especially sudden changes in your mood, behaviors, thoughts, or feelings, or if you have depression or thoughts of suicide.
- **Low blood sugar:** Weight loss can cause low blood sugar in people taking medicines for type 2 diabetes, such as insulin or sulfonylureas. Blood sugar levels should be checked before and while taking BELVIQ. Changes to diabetes medication may be needed if low blood sugar develops.
- **Painful erections:** If you have an erection lasting more than 4 hours while on BELVIQ, stop taking BELVIQ and call your doctor or go to the nearest emergency room right away.
- **Slow heartbeat:** BELVIQ may cause your heart to beat slower.
- **Decreases in blood cell count:** BELVIQ may cause your red and white blood cell counts to decrease.
- **Increase in prolactin:** BELVIQ may increase the amount of a hormone called prolactin. Tell your doctor if your breasts begin to make milk or a milky fluid, or if you are a male and your breasts increase in size.
- **Most common side effects of BELVIQ® include:** Headache, dizziness, fatigue, nausea, dry mouth, constipation, cough, low blood sugar (hypoglycemia) in patients with diabetes, and back pain.
- **Nursing:** BELVIQ should not be taken while breastfeeding.
- **Drug interactions:** Before taking BELVIQ, tell your doctor if you take medicines for depression, migraines, or other medical conditions, such as: triptans; medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, selective serotonin reuptake inhibitors, selective serotonin-norepinephrine reuptake inhibitors, monoamine oxidase inhibitors, or antipsychotics; cabergoline; linezolid (an antibiotic); tramadol; dextromethorphan (an over-the-counter (OTC) common cold/cough medicine); OTC supplements such as tryptophan or St. John's Wort; or erectile dysfunction medicines.
- BELVIQ is a federally controlled substance (CIV) because it may be abused or lead to drug dependence.

For more information about BELVIQ®, talk to your healthcare professional and see the Patient Information on the reverse side.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.



You've got your goals and
You've got **BELVIQ**®

FDA approved for *weight loss*

Adding BELVIQ® to your healthy routine may help you take weight loss further and may help lower blood pressure.* In clinical studies, BELVIQ® helped some people **lose weight and keep it off** more effectively compared with diet and exercise alone.† **Ask your healthcare professional if BELVIQ® is right for you.**

 **BELVIQ**®
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*Though it is not a blood pressure treatment, BELVIQ may lower blood pressure.

†BELVIQ was evaluated in 3 clinical studies involving overweight adults (with at least 1 weight-related medical condition) and obese adults. All 3 studies compared people taking BELVIQ plus diet and exercise to people using diet and exercise alone (placebo). The results of the first 2 studies (involving 7,190 people without diabetes) showed that 47.1% of people taking BELVIQ lost 5% or more of their body weight compared with 22.6% of the placebo group. People taking BELVIQ also had significant improvements in their blood pressure and cholesterol levels. A third clinical study (involving 604 overweight people with type 2 diabetes) showed that 37.5% of people taking BELVIQ lost 5% or more of their body weight compared with 16.1% of the placebo group. People taking BELVIQ also had significant improvements in their blood sugar levels. Nearly one-half of all participants completed the first 2 studies; nearly two-thirds of the participants completed the third study.

‡Restrictions apply.

IMPORTANT PATIENT INFORMATION

Read the Patient Information that comes with BELVIQ® (BEL-VEEK) before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about BELVIQ, talk to your doctor or pharmacist.

What is BELVIQ?

BELVIQ is a prescription medicine that may help some obese adults or overweight adults who also have weight related medical problems lose weight and keep the weight off.

BELVIQ should be used with a reduced calorie diet and increased physical activity.

It is not known if BELVIQ is safe and effective when taken with other prescription, over-the-counter, or herbal weight loss products.

It is not known if BELVIQ changes your risk of heart problems or stroke or of death due to heart problems or stroke.

It is not known if BELVIQ is safe when taken with some other medicines that treat depression, migraines, mental problems, or the common cold (serotonergic or antidopaminergic agents).

It is not known if BELVIQ is safe and effective in children under 18 years old.

BELVIQ is a federally controlled substance (CIV) because it contains lorcaserin hydrochloride and may be abused or lead to drug dependence. Keep your BELVIQ in a safe place, to protect it from theft. Never give your BELVIQ to anyone else, because it may cause harm to them. Selling or giving away this medicine is against the law.

Who should not take BELVIQ?

Do not take BELVIQ if you:

- are pregnant or planning to become pregnant. BELVIQ may harm your unborn baby.
- are allergic to lorcaserin hydrochloride or any of the ingredients in BELVIQ. See the end of this leaflet for a complete list of ingredients in BELVIQ.

What should I tell my healthcare provider before taking BELVIQ?

Before you take BELVIQ, tell your doctor if you:

- **have or have had heart problems including:**
 - congestive heart failure
 - heart valve problems
 - slow heart beat or heart block
- have diabetes
- have a condition such as sickle cell anemia, multiple myeloma, or leukemia
- have a deformed penis, Peyronie's disease, or ever had an erection that lasted more than 4 hours
- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant.
- are breast feeding or plan to breastfeed. It is not known if BELVIQ passes into your breastmilk. You and your doctor should decide if you will take BELVIQ or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

BELVIQ may affect the way other medicines work, and other medicines may affect how BELVIQ works.

Especially tell your doctor if you take medicines for depression, migraines or other medical conditions such as:

- triptans, used to treat migraine headache
- medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, selective serotonin uptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs), or antipsychotics
- cabergoline
- linezolid, an antibiotic

- tramadol
- dextromethorphan, an over-the-counter medicine used to treat the common cold or cough
- over-the-counter supplements such as tryptophan or St. John's Wort
- medicines to treat erectile dysfunction
- Ask your doctor or pharmacist for a list of these medicines, if you are not sure.
- Know all the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take BELVIQ?

- Take BELVIQ exactly as your doctor tells you to take it.
- Your doctor will tell you how much BELVIQ to take and when to take it.
 - Take 1 tablet 2 times each day.
 - **Do not** increase your dose of BELVIQ.
 - BELVIQ can be taken with or without food.
- Your doctor should start you on a diet and exercise program when you start taking BELVIQ. Stay on this program while you are taking BELVIQ.
- Your doctor should tell you to stop taking BELVIQ if you do not lose a certain amount of weight within the first 12 weeks of treatment.
- If you take too much BELVIQ or overdose, call your doctor or go to the nearest emergency room right away.

What should I avoid while taking BELVIQ?

Do not drive a car or operate heavy machinery until you know how BELVIQ affects you. BELVIQ can slow your thinking.

What are the possible side effects of BELVIQ?

BELVIQ may cause serious side effects, including:

- **Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions.** BELVIQ and certain medicines for depression, migraine, the common cold, or other medical problems may affect each other causing serious or life-threatening side effects. Call your doctor right away if you start to have any of the following symptoms while taking BELVIQ:
 - mental changes such as agitation, hallucinations, confusion, or other changes in mental status
 - coordination problems, uncontrolled muscle spasms, or muscle twitching (overactive reflexes)
 - restlessness
 - racing or fast heart beat, high or low blood pressure
 - sweating or fever
 - nausea, vomiting, or diarrhea
 - muscle rigidity (stiff muscles)
- **Valvular heart disease.** Some people taking medicines like BELVIQ have had problems with the valves in their heart. Call your doctor right away if you have any of the following symptoms while taking BELVIQ:
 - trouble breathing
 - swelling of the arms, legs, ankles, or feet
 - dizziness, fatigue, or weakness that will not go away
 - fast or irregular heartbeat
- **Changes in your attention or memory.**
- **Mental problems.** Taking BELVIQ in high doses may cause psychiatric problems such as:
 - hallucinations
 - feeling high or in a very good mood (euphoria)
 - feelings of standing next to yourself or out of your body (disassociation)
- **Depression or thoughts of suicide.** You should pay attention to any mental changes, especially sudden changes, in your mood, behaviors, thoughts, or feelings. Call your healthcare provider right away if you have any mental changes that are new, worse, or worry you.
- **Low blood sugar (hypoglycemia) in people with type 2 diabetes mellitus who also take medicines used to treat type 2 diabetes mellitus.** Weight loss can cause low blood sugar in

people with type 2 diabetes mellitus who also take medicines used to treat type 2 diabetes mellitus (such as insulin or sulfonylureas). You should check your blood sugar before you start taking BELVIQ and while you take BELVIQ.

- **Painful erections (priapism).** The medicine in BELVIQ can cause painful erections that last more than 6 hours. If you have an erection lasting more than 4 hours whether it is painful or not, stop using BELVIQ and call your doctor or go to the nearest emergency room right away.
- **Slow heart beat.** BELVIQ may cause your heart to beat slower. Tell your doctor if you have a history of your heart beating slow or heart block.
- **Decreases in your blood cell count.** BELVIQ may cause your red and white blood cell count to decrease. Your doctor may do tests to check your blood cell count while you are taking BELVIQ.
- **Increase in prolactin.** The medicine in BELVIQ may increase the amount of a certain hormone your body makes called prolactin. Tell your doctor if your breasts begin to make milk or a milky discharge or if you are a male and your breasts begin to increase in size.
- The most common side effects of BELVIQ include:
 - headache
 - constipation
 - dizziness
 - cough
 - fatigue
 - low blood sugar (hypoglycemia) in patients with diabetes
 - nausea
 - back pain
 - dry mouth

Tell to your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of BELVIQ. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088.

How do I store BELVIQ?

Store BELVIQ at room temperature between 59°F to 86°F (15°C to 30°C).

Safely throw away medicine that is out of date or no longer needed.

Keep BELVIQ and all medicines out of the reach of children.

General information about the safe and effective use of BELVIQ.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use BELVIQ for a condition for which it was not prescribed. Do not give BELVIQ to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about BELVIQ. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about BELVIQ that is written for health professionals.

For more information, go to www.BELVIQ.com Website or call 1-888-274-2378.

What are the ingredients in BELVIQ?

Active Ingredient: lorcaserin hydrochloride

Inactive Ingredients: silicified microcrystalline cellulose; hydroxypropyl cellulose NF; croscarmellose sodium NF; colloidal silicon dioxide NF; polyvinyl alcohol USP; polyethylene glycol NF; titanium dioxide USP; talc USP; FD&C Blue #2 aluminum lake; and magnesium stearate NF.

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A few additional symptoms of rapid weight-loss to watch for include:

- **Fatigue** – Due to low energy intake
- **Headaches** – Often caused by dehydration
- **Hair loss** – Usually transient, but your doctor should check your thyroid levels
- **Dizziness** – Due to dehydration, low blood pressure, or low blood sugar as described on page 17
- **Constipation** – Due to dehydration or increased protein in nutritional plan

Rapid weight-loss is just like other health decisions we try to make. It is a matter of weighing the risks versus the benefits. If you and your doctor decide together that you can manage a VLCD or surgical intervention, and that you can maintain follow-up with your healthcare provider, these options are tolerable and the adverse side effects can usually be managed appropriately.

Here are some key points to remember as you consider all of your options:

1. **Have a Plan** – You need a plan to transition off the rapid weight-loss intervention as you approach your goals. This long-term plan needs to be sustainable for you and your lifestyle.
2. **Consider Medication** – There are FDA-approved anti-obesity medications which can help with the rate of weight-loss by controlling hunger and satiety, regardless of whether you choose a moderate rate or rapid rate plan.

Evidence is mounting that these anti-obesity medications are just as important during weight maintenance as they are in active weight-loss. Anti-obesity medications do work, so use them!

3. **Obesity is a Chronic Disease** – This is the most important concept – no matter how you choose to approach the disease. While treating any disease brings risk, obesity itself is associated with 236 other diseases – that is real risk.

It's not your fault – it's your physiology. Chronic disease requires chronic management and this is where it does become YOUR responsibility to seek care and partner with your doctor to manage your health. Together, you can plan for active phase and maintenance phase treatments that are individualized to you and optimize the benefit versus risk ratio. With many pathways to achieve your goals, the most important thing is to start the conversation today!

About the Author:

Deborah Horn, DO, MPH, MFOMA, is the President of the Obesity Medicine Association and Clinical Assistant Professor in the Department of Surgery at The University of Texas McGovern Medical School at Houston. She is the Medical Director for the UTHealth Center for Obesity Medicine and Metabolic Performance. Dr. Horn was also the recipient of the OAC's Healthcare Provider Advocate of the Year award, an award given to a healthcare provider who is a tireless advocate for patients, the OAC and the cause of obesity.

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List as of 3/30/17