Drug Facts

BELVIQ (lorcaserin) **for weight loss in adults who are overweight** (with weight-related health problems) **or obese**

What is this drug for?	To help people lose weight, when combined with exercise and a reduced-calorie diet. If you don't lose at least 5% of your body weight after 3 months, stop taking the drug, because it is unlikely to work.
Who might consider taking it?	Adults who are **overweight** (with a Body Mass Index of 27 to 29.9) and also have a weight-related health problem such as high blood pressure, high cholesterol, heart disease, type 2 diabetes, or sleep apnea; or people who are **obese** (with a BMI of 30 or higher). You can calculate your BMI at **consumerreports.org/bmi.**
When was the drug approved?	**June 2012** (based on studies totaling about 6,600 people, including about 3,500 people who actually took BELVIQ and the rest of whom took a placebo).
What precautions should I take?	Avoid taking BELVIQ with other drugs known to raise serotonin levels because that can cause a dangerous overdose. That includes many antidepressants, anxiety, or mania drugs, such as SSRIs (like Prozac), SNRIs (like Effexor), MAOIs (including the antibiotic linezolid), tricyclic antidepressants, bupropion, lithium, tramadol, tryptophan, and St. John's wort; triptans (such as Imitrex), used to treat migraine and cluster headaches; and dextromethorphan, found in many cough medicines.
What other choices are there?	Diet or exercise programs, other medications approved for weight loss, and weight loss surgery for patients with severe obesity (BMI greater than 40).

STUDY FINDINGS: NO DIABETES (combined results of 2 identical trials)

Participants: 6,136 people **without diabetes**. Most were women, ages 18 to 65 years, with an average weight of 221 pounds, who were either overweight and had weight-related health problems or were obese. They were randomized to either BELVIQ or PLACEBO for 1 year. Here's what happened:

	BELVIQ (10 mg twice a day)	vs.	PLACEBO (No drug)
Both groups were counseled to:	**Eat a reduced-calorie diet** (600 fewer calories/day) **Exercise** at moderate level 30 minutes a day		
How did BELVIQ help?			
Average amount of weight lost at 1 year			
The typical person on BELVIQ lost **3% more weight** (6 pounds) than the typical person on PLACEBO	Lost 6% of weight (13 pounds lost)	vs.	Lost 3% of weight (7 pounds lost)
Percent of people who lost various amounts of weight			
11% more people on BELVIQ lost between 5% and 9% of their weight (11 to 21 pounds) than with PLACEBO	25%	vs.	14%
10% more people on BELVIQ lost between 10% and 19% of their weight (22 to 43 pounds) than with PLACEBO	18%	vs.	8%
3% more people on BELVIQ lost 20% or more of their weight (44 or more pounds) than with PLACEBO	4%	vs.	1%
What were BELVIQ'S side effects?			
Serious side effects			
0.4% more people had leaky aortic or mitral valves	2.4%	vs.	2%
1.4% more had memory or attention problems	1.9%	vs.	0.5%
Symptom side effects			
7% more people had headache	17%	vs.	10%
5% more had dizziness	9%	vs.	4%
3% more had nausea	8%	vs.	5%
3% more had fatigue	7%	vs.	4%
3% more had dry mouth	5%	vs.	2%
2% more had constipation	6%	vs.	4%

STUDY FINDINGS: DIABETES

Participants: 499 men and women **with diabetes**. They were between the ages of 18 to 65 years, with an average HbA1c of 8% and an average weight of 228 pounds, and were either overweight and had weight-related health problems or were obese. They were randomized to either BELVIQ or PLACEBO for 1 year. Here's what happened:

	BELVIQ (10 mg twice a day)	vs.	PLACEBO (No drug)
Both groups were counseled to:	**Eat a reduced-calorie diet** (600 fewer calories/day) **Exercise** at moderate level 30 minutes a day		
How did BELVIQ help?			
Average amount of weight lost at 1 year			
The typical person on BELVIQ **lost 3% more weight** (6 pounds) than the typical person on PLACEBO.	Lost 5% of weight (11 pound lost)	vs.	Lost 2% of weight (5 pound lost)
Percent of people who lost various amounts of weight			
9% more people on BELVIQ lost between 5% and 9% (11 to 22 pounds) of their weight than with PLACEBO	21%	vs.	12%
11% more people on BELVIQ lost between 10% and 19% of their weight than with PLACEBO	15%	vs.	4%
1% more people on BELVQ lost more than 20% of their weight (45 or more pounds) than with PLACEBO	1%	vs.	0%
Average blood sugar (HbA1c) was 0.5 lower than placebo	0.9% lower	vs.	0.4% lower
What were BELVIQ'S side effects?			
Serious side effects			
0.4% more people had leaky heart valves	2.4%	vs.	2%
1.4% more had memory or attention problems	1.9%	vs.	0.5%
Symptom side effects			
8% more people had low blood sugar (none required treatment)	29%	vs.	21%
8% more had headache	15%	vs.	7%
4% more had back pain	12%	vs.	8%
4% more had cough	8%	vs.	4%
3% more had fatigue	7%	vs.	4%

WARNINGS ABOUT UNCOMMON LIFE-THREATENING AND VERY SERIOUS SIDE EFFECTS

Other weight-loss drugs that act on the central nervous system and specifically on the serotonin system, like BELVIQ, have been associated with pulmonary hypertension, Serotonin Syndrome (muscle rigidity, fever, and seizures), Neuroleptic Malignant Syndrome (very high fever and blood pressure combined with delirium), depression, suicidal thoughts, and painful erection lasting more than 4 hours. The FDA is also concerned about: euphoria and dissociation; heart rate decreases; decreased red and white blood cell counts; hypoglycemia in patients with Type 2 diabetes on treatment; and elevated prolactin levels.

Bottom line

Limited benefit "The efficacy of lorcaserin [BELVIQ] is not impressive but also is not out of line with other weight loss drugs ... a small proportion of patients may achieve impressive and probably quite important weight loss. Unfortunately, this will not be the experience of the majority of users" -- Director, FDA Office of Drug Evaluation. Office Director's Memo: Summary Review.

The nearly identical weight-loss findings for the FDA-approval studies above make the benefit numbers more believable. But the only long-term (2-year) study showed that people on the drug gained some weight back after the first year**.** No study has shown that BELVIQ prevents heart problems or strokes, a major reason to treat obesity.

Concern about serious harm The FDA is requiring the company to conduct a large trial to learn the drug's effect on heart attacks, strokes, and heart valve problems. The European Medicines Agency said approval was unlikely because it thought benefits did not outweigh harms, including possible cancers, psychiatric disorders, and heart valve problems.

Concern about new drugs As with all new drugs, important side effects may emerge after the drug is on the market, when larger numbers of people—some with other conditions and on other medications—use the new drug. Since this is the first drug of its kind to receive FDA approval, experience is particularly limited.