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Product Fact Sheet

About BELVIQ®

BELVIQ is a treatment option for chronic weight management for overweight patients with at least one weight-related comorbidity or obese patients.

BELVIQ is used along with a reduced-calorie diet and increased physical activity for chronic weight management in adults who have a:

- Body mass index (BMI) of 30 kg/m^2 or greater (obese) or
- BMI of 27 kg/m^2 or greater (overweight) with at least one weight-related medical condition such as high blood pressure, high cholesterol, or type 2 diabetes.

Limitations of Use:

- The safety and effectiveness of BELVIQ in combination with prescription, over-the-counter, and herbal weight loss products is not known.
- It is not known if BELVIQ changes your risk of heart problems or stroke, or death due to heart problems or stroke.

BELVIQ is a federally controlled substance (CIV) because it may be abused or lead to drug dependence.

Mechanism of Action

BELVIQ is believed to decrease food consumption and promote satiety by selectively activating serotonin 2C receptors in the brain. The exact mechanism of action of BELVIQ is not known.

Important Safety Information

Important Safety Information:

- **Pregnancy:** Do not take BELVIQ if you are pregnant or planning to become pregnant. BELVIQ may harm your unborn baby, as weight loss offers no potential benefit to a pregnant woman.
- **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, feeling high or in a very good mood, or feelings of standing outside of 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.

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BELVIQ EFFICACY AND SAFETY

The safety and efficacy of BELVIQ for chronic weight management in conjunction with a reduced-calorie diet and increased physical activity were evaluated in three double-blind, randomized, placebo-controlled trials with durations ranging from 52 to 104 weeks:

- **BLOOM** (**B**ehavioral modification and **L**orcaserin for **O**verweight and **O**besity **M**anagement)
- **BLOSSOM** (**B**ehavioral modification and **LO**rcaserin **S**econd **S**tudy for **O**besity **M**anagement)
- **BLOOM-DM** (**B**ehavioral modification and **L**orcaserin for **O**verweight and **O**besity Management in **D**iabetes **M**ellitus)

All three trials included a lifestyle modification program including a standardized program of a reduced-calorie diet, increased physical activity and behavioral counseling for both the placebo and BELVIQ groups.

Two trials in overweight adults without diabetes and one trial in overweight adults with type 2 diabetes evaluated the safety and efficacy of BELVIQ 10 mg twice daily. The primary efficacy parameter in these trials was weight loss at one year, which was assessed by the percent of patients achieving greater than or equal to five percent weight loss, percent of patients achieving greater than or equal to 10 percent weight loss, and average weight loss.

In the clinical trials with patients without diabetes, (total patients =7,190)

- **47.1** percent of patients on BELVIQ BID along with a reduced-calorie diet and increased physical activity lost greater than or equal to five percent body weight vs. 22.6 percent of patients who only followed a reduced-calorie diet and increased physical activity at one year.
- **22.4** percent of patients on BELVIQ BID along with a reduced-calorie diet and increased physical activity lost greater than or equal to ten percent body weight vs. 8.7 percent of patients who only followed a reduced-calorie diet and increased physical activity at one year.
- The average weight loss for patients on BELVIQ BID was **5.8** percent vs. an average weight loss of 2.5 percent for patients who only followed a reduced-calorie diet and increased physical activity (placebo).
- 44 percent of patients on BELVIQ BID and 51 percent of placebo patients withdrew prior to week 52.

Most common side effects in patients without diabetes: Headache, dizziness, fatigue, nausea, dry mouth, and constipation.

Response to therapy should be evaluated by week 12. If a patient has not lost at least 5 percent of baseline body weight, discontinue BELVIQ, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

IMPORTANT SAFETY INFORMATION

Important Safety Information (continued):

- **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 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.
- **Decreases in blood cell count:** BELVIQ may cause your red and white blood cell count to decrease.

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BELVIQ EFFICACY AND SAFETY (CONTINUED)	In the clinical trials with patients with type 2 diabetes, (total patients = 604) • **37.5** percent of patients on BELVIQ along with a reduced-calorie diet and increased physical activity lost greater than or equal to five percent body weight vs. 16.1 percent of patients who only followed a reduced-calorie diet and increased physical activity at one year. • **16.3** percent of patients on BELVIQ along with a reduced-calorie diet and increased physical activity lost greater than or equal to ten percent body weight vs. 4.4 percent of patients who only followed a reduced-calorie diet and increased physical activity at one year. • The average weight loss for patients with type 2 diabetes on BELVIQ was **4.5** percent vs. 1.5 percent for patients who only followed a reduced-calorie diet and increased physical activity (placebo). • 34 percent of patients on BELVIQ and 38 percent of placebo patients withdrew prior to week 52. **Most common side effects in patients with diabetes:** Low blood sugar, headache, back pain, cough, and fatigue.
DOSING AND ADMINISTRATION	For appropriate patients who have been evaluated by their physicians, the recommended dose of BELVIQ is 10 mg, taken twice daily. BELVIQ can be taken with or without food. Response to therapy should be evaluated by week 12. If a patient has not lost at least 5 percent of baseline body weight, discontinue BELVIQ, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.
MORE INFORMATION	For additional product information, please call Eisai Medical Information at 1-888-274-2378 or visit www.BELVIQ.com.
MANUFACTURING AND U.S. MARKETING	BELVIQ is marketed in the U.S. by Eisai Inc. and manufactured by Arena Pharmaceuticals.
IMPORTANT SAFETY INFORMATION	**Important Safety Information (continued):** • **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 begin to increase in size. • **Most common side effects in patients without diabetes:** Headache, dizziness, fatigue, nausea, dry mouth, and constipation. • **Most common side effects in patients with diabetes:** Low blood sugar, headache, back pain, cough, and fatigue. • **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. For more information about BELVIQ, see the Full Product Information at www.BELVIQ.com.

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