FDA Approves New Anti-Obesity Drug

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Contrave, a combination of naltrexone and buproprion, has been approved for long-term weight loss management in overweight and obese adults.

Earlier this month, the U.S. Food and Drug Administration approved Contrave (naltrexone hydrochloride and bupropion hydrochloride extended-release tablets) for long-term weight management in addition to a reduced-calorie diet and physical activity.

Who's It For?
Contrave is intended for use in adults with a body mass index (BMI) of 30 or greater (obesity). It's also approved for adults with a BMI of 27 or greater (overweight) with at least one weight-related condition, such as hypertension, type 2 diabetes mellitus, or dyslipidemia.

“Obesity continues to be a major public health concern,” said Jean-Marc Guettier, MD, director of the Division of Metabolism and Endocrinology Products in FDA’s Center for Drug Evaluation and Research. “When used as directed in combination with a healthy lifestyle that includes a reduced-calorie diet and exercise, Contrave provides another treatment option for chronic weight management for people who are obese or are overweight and have at least one weight-related health condition.”

What Is It?
Contrave is a combination of two FDA-approved drugs, naltrexone and bupropion, in an extended-release formulation. Naltrexone is approved to treat alcohol and opioid dependence. Bupropion is approved to treat depression and seasonal affective disorder and as an aid to smoking cessation treatment.

How Effective Is It?
The effectiveness of Contrave was evaluated in multiple clinical trials that included approximately 4,500 obese and overweight patients with and without significant weight-related conditions treated for one year. All patients received lifestyle modification that consisted of a reduced-calorie diet and regular physical activity.

In patients without diabetes, those taking Contrave had an average weight loss of 4.1% over treatment with placebo (inactive pill) at one year. Specifically, 42% of patients treated with Contrave lost at least 5% of their body weight, compared with 17% of patients treated with placebo.

Results from another clinical trial that enrolled patients with type 2 diabetes showed that patients had an average weight loss of 2% over treatment with placebo at one year. In this trial, 36% of patients treated with Contrave lost at least 5% of their body weight, compared with 18% of patients treated with placebo.

When to Discontinue?
Patients using Contrave at the maintenance dose should be evaluated after 12 weeks to determine if the treatment is working. If a patient has not lost at least 5% of baseline body weight, Contrave should be discontinued, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

Adverse Effects

Suicidal thoughts. Because it contains bupropion, Contrave has a boxed warning for an increased risk of suicidal thoughts and behaviors associated with antidepressant drugs. The warning also notes that serious neuropsychiatric events have been reported in patients taking bupropion for smoking cessation.

Seizures. Contrave can cause seizures and must not be used in patients who have seizure disorders. The risk of seizure is dose-related. Contrave should be discontinued and not restarted in patients who experience a seizure while taking Contrave.

High blood pressure. Contrave can also raise blood pressure and heart rate and must not be used in patients with uncontrolled high blood pressure. The clinical significance of the increases in blood
pressure and heart rate observed with Contrave treatment is unclear, especially for patients with heart-related and cerebrovascular (blood vessel dysfunction impacting the brain) disease, since patients with a history of heart attack or stroke in the previous six months, life-threatening arrhythmias, or congestive heart failure were excluded from the clinical trials. Blood pressure and heart rate should be measured prior to starting the drug and should be monitored at regular intervals, particularly among patients with controlled high blood pressure prior to treatment. 

**Most common.** The most common adverse reactions reported with Contrave include nausea, constipation, headache, vomiting, dizziness, insomnia, dry mouth, and diarrhea.

**Contraindications**

Other products containing bupropion should not be taken along with Contrave. The drug should not be used in patients who have eating disorders (bulimia or anorexia nervosa). Contrave should also not be taken by patients who are using opioids or treatments for opioid dependence, or who are experiencing acute opiate withdrawal. Patients undergoing an abrupt discontinuation of alcohol, benzodiazepines, barbiturates and antiepileptic drugs should not take Contrave. Women who are pregnant or trying to become pregnant should not take Contrave. 

Contrave is distributed by Takeda Pharmaceuticals America Inc. of Deerfield, Illinois, for Orexigen Therapeutics, Inc. of La Jolla, California.

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