

Indication

CONTRAVE (naltrexone HCl/bupropion HCl) is a prescription weight-loss medicine that may help adults with obesity (BMI greater than or equal to 30 kg/m²), or adults who are overweight (BMI greater than or equal to 27 kg/m²) with at least one weight-related medical condition, lose weight and keep the weight off. CONTRAVE should be used along with diet and exercise.

Important Safety Information

One of the ingredients in CONTRAVE, bupropion, may increase the risk of suicidal thinking in children, adolescents, and young adults. CONTRAVE patients should be monitored for suicidal thoughts and behaviors. In patients taking bupropion for smoking cessation, serious neuropsychiatric adverse events have been reported. **CONTRAVE is not approved for children under 18.**

Stop taking CONTRAVE and call your healthcare provider right away if you experience:

- thoughts about suicide or dying
- depression or anxiety
- panic attacks
- trouble sleeping
- irritability
- aggression
- mania
- other unusual changes in behavior or mood

Do not take CONTRAVE if you: have uncontrolled high blood pressure; have or have had seizures or an eating disorder; use other medicines that contain bupropion; are dependent on opioid pain medicines, use medicines to help stop taking opioids, or are in opiate withdrawal; drink a lot of alcohol and abruptly stop drinking, or take sedatives, benzodiazepines, or anti-seizure medicines and you abruptly stop using them; or are taking monoamine oxidase inhibitors (MAOIs). **Do not start CONTRAVE until you have stopped taking your MAOI for at least 14 days.** Do not take CONTRAVE if you are allergic to any of the ingredients in CONTRAVE. Do not take CONTRAVE if you are pregnant or planning to become pregnant or are breastfeeding.

Before taking CONTRAVE, tell your healthcare provider about all of your current or past health conditions.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Do not take any other medicines while you are taking CONTRAVE unless your healthcare provider says it is okay.

If you have a seizure while taking CONTRAVE, stop taking CONTRAVE and call your healthcare provider right away.

Additional serious side effects may include:

- opioid overdose or sudden opioid withdrawal
- severe allergic reactions
- increases in blood pressure or heart rate
- liver damage or hepatitis
- manic episodes
- visual problems (glaucoma)
- increased risk of low blood sugar (hypoglycemia) in people with type 2 diabetes mellitus who take certain medicines to treat their diabetes

The most common side effects of CONTRAVE include nausea, constipation, headache, vomiting, dizziness, trouble sleeping, dry mouth, and diarrhea.

These are not all the possible side effects of CONTRAVE. Please refer to the [full Prescribing Information, including Medication Guide, –or– Brief Summary of Information] for CONTRAVE [on the following page –or– at XX location] or talk to your doctor.

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