Contrave®
(naltrexone HCl/bupropion HCl)
8 mg/90 mg • Extended-Release Tablets

Moving beyond a one-size-fits-all approach to weight-loss treatment[1]

Taking an individualized approach to selecting antiobesity medications (AOMs)[1]

Help patients achieve sustained weight loss with the proven efficacy of CONTRAVE[2,3]

Indication

CONTRAVE is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obese) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia)

Limitations of Use

The effect of CONTRAVE on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of CONTRAVE in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Suicidality and Antidepressant Drugs

CONTRAVE® is not approved for use in the treatment of major depressive disorder or other psychiatric disorders. CONTRAVE contains bupropion, the same active ingredient as some other antidepressant medications (including, but not limited to, WELLBUTRIN, WELLBUTRIN SR, WELLBUTRIN XL, and APLENZIN). Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term trials. These trials did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in subjects over age 24; there was a reduction in risk with antidepressant use in subjects aged 65 and older. In patients of all ages who are started on CONTRAVE, monitor closely for worsening, and for the emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber. CONTRAVE is not approved for use in pediatric patients.

Please see Important Safety Information throughout and the Full Prescribing Information, including Medication Guide, for CONTRAVE.

An individualized approach to AOM selection may help patients with obesity have better weight-loss outcomes[1]

The Acosta et al observational study evaluated whether choosing AOM based on a patient's obesity-related characteristics would lead to greater weight loss compared with a more conventional approach[1]

STUDY DESIGN: an observational study based on 2 cohorts

1

COHORT 1

450 patients with obesity (BMI >30 kg/m^2) underwent obesity phenotype testing and were classified into 4 obesity phenotypes (Hungry Brain™, Hungry Gut™, Emotional Hunger™, and Slow Burn™).[1*]

The primary goal was to identify and classify obesity phenotypes.[1]

Obesity type characterization and classification[1]:

- Obesity phenotypes were assigned to patients based on a number of factors, including body composition, resting energy expenditure, satiety, satiation, eating behavior, affect, and physical activity[1]

The aim of this part of the study was to characterize obesity phenotypes in order to assess their potential for individualizing therapy for obesity.[1]

*15% of participants could not be classified into 1 of the 4 phenotypes.[1]

IMPORTANT SAFETY INFORMATION (CONT'D)

Contraindications

CONTRAVE is contraindicated in: uncontrolled hypertension; seizure disorder or a history of seizures; use of other bupropion-containing products; bulimia or anorexia nervosa, which increase the risk for seizure; chronic opioid or opiate agonist (eg, methadone) or partial agonist (eg, buprenorphine) use, or acute opiate withdrawal; patients undergoing an abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs; use during/within 14 days following treatment with monoamine oxidase inhibitors (MAOIs), as there is an increased risk of hypertensive reactions when CONTRAVE is used concomitantly with MAOIs, including reversible MAOIs such as linezolid or intravenous methylene blue; known allergy to any component of CONTRAVE, as anaphylactoid/anaphylactic reactions and Stevens-Johnson syndrome have been reported.

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2

COHORT 2

312 patients were assigned to phenotype-guided treatment (n=84 cases) or non–phenotype-guided treatment (n=228 controls) with AOMs, in addition to diet and exercise recommendations.[1]

Participants included patients with a BMI ≥27 kg/m^2 with adiposity-related comorbidities or patients with a BMI ≥30 kg/m^2 with or without adiposity-related comorbidities.[1]

The primary outcome was the percent of total body weight loss at 12 months.[1]

- All patients were encouraged to participate in a 12-week behavioral program to reduce dietary intake, reach a goal of 10,000 or more steps a day, get at least 150 minutes of cardiovascular exercise per week, and limit consumption of liquid calories[1]

Individualized treatment with AOMs:

- Treatment decisions in the phenotype-guided treatment group were based on the mechanism of action of the AOMs and the results of randomized, placebo-controlled trials[1]

Disclaimer: this study was not sponsored by Currax Pharmaceuticals LLC. There are no randomized, controlled, head-to-head studies comparing the safety or efficacy of CONTRAVE with other AOMs.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

Suicidal Behavior and Ideation

All patients being treated with antidepressants for any indication should be monitored and observed for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes.

Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of suicidality, anxiety, agitation, irritability, unusual changes in behavior, and other symptoms, and to report such symptoms immediately to healthcare providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for CONTRAVE should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

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In the Acosta et al study, selection of AOMs was guided by obesity type[1]

Prevalence of participants' phenotype in the phenotype-guided group (n=84/312)[1]

HUNGRY BRAIN™ Satiation	HUNGRY GUT™ Satiety	EMOTIONAL HUNGER™ Emotional/reward	SLOW BURN™ Energy expenditure
More calories consumed per meal	Appetite returns more quickly after a meal	Eating to cope with positive or negative emotions	Decreased metabolic rate
			
40% of patients	**18%** of patients	**30%** of patients	**12%** of patients
Tx: phentermine/topiramate	**Tx:** liraglutide	**Tx:** CONTRAVE (naltrexone/bupropion ER)	**Tx:** phentermine and increased resistance training

CONTRAVE was selected for the emotional hunger type of obesity because the mechanism of action modulates appetite and cravings[1]*

*The exact neurochemical effects of CONTRAVE leading to weight loss are not fully understood.[2]

Tx=treatment.

IMPORTANT SAFETY INFORMATION (CONT'D)

Neuropsychiatric Adverse Events and Suicide Risk in Smoking Cessation Treatment

CONTRAVE is not approved for smoking cessation. Serious neuropsychiatric adverse events have been reported in patients taking bupropion for smoking cessation. These postmarketing reports have included changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide.

Some patients who stopped smoking may have been experiencing symptoms of nicotine withdrawal, including depressed mood. Depression, rarely including suicidal ideation, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these adverse events occurred in patients taking bupropion who continued to smoke.

Neuropsychiatric adverse events occurred in patients without and with pre-existing psychiatric disease; some patients experienced worsening of their psychiatric illnesses. Observe patients for the occurrence of neuropsychiatric adverse events. Advise patients and caregivers that the patient should stop taking CONTRAVE and contact a healthcare provider immediately if agitation, depressed mood, or changes in behavior or thinking that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior.

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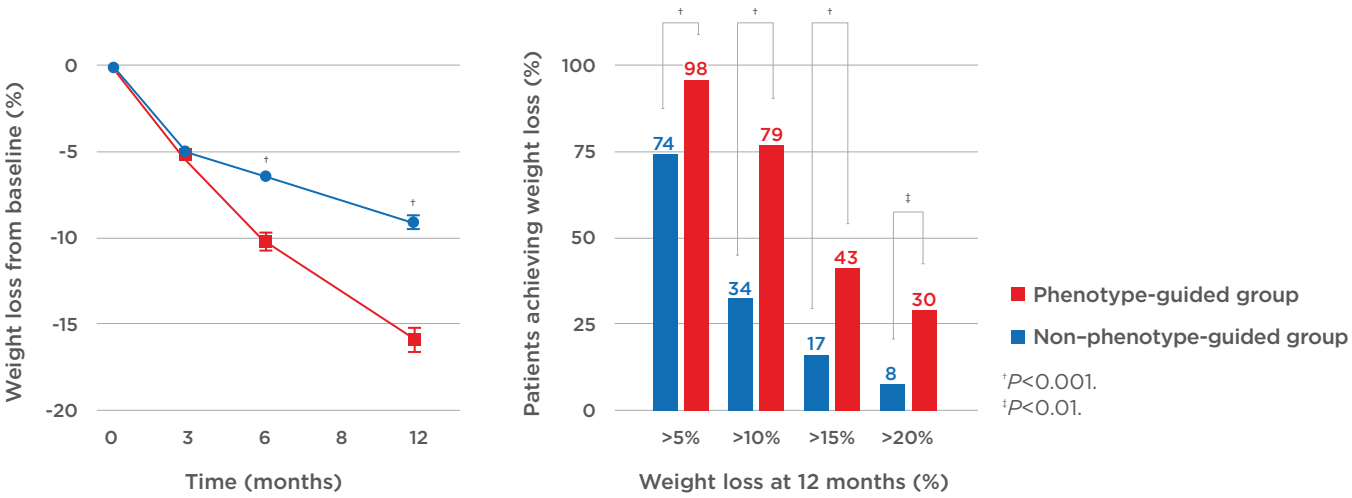
The individualized treatment approach significantly improved weight-loss outcomes[1]



- **In the observational comparison of 2 samples of patients, the phenotype-guided approach was associated with 1.75-fold greater weight loss after 12 months with a mean weight loss of -15.9% compared with -9.0% in the non–phenotype-guided group (*P*<0.001)[1]**

Study limitations: outcomes require replication and validation in larger, more racially and metabolically diverse cohorts, such as multicenter, randomized studies. This outcome with phenotype-guided pharmacotherapy has limitations that deserve further study, including appraising a "testing bias." Participants who underwent additional testing may be conditioned to greater responsiveness based on clinical education and consent, lack of blinded randomization, and potential group-difference confounders, such as age and comorbidities.[1]

IMPORTANT SAFETY INFORMATION (CONT'D)

Seizures

Bupropion, a component of CONTRAVE, can cause seizures. The risk of seizure is dose-related. Discontinue treatment and do not restart CONTRAVE in patients who experience a seizure. Use caution when prescribing CONTRAVE to patients with an elevated risk of seizure, including: history of head trauma or prior seizure, severe stroke, arteriovenous malformation, central nervous system tumor or infection, or metabolic disorders (eg, hypoglycemia, hyponatremia, severe hepatic impairment, and hypoxia); excessive use of alcohol or sedatives, addiction to cocaine or stimulants, or withdrawal from sedatives; patients with diabetes treated with insulin and/or oral diabetic medications (sulfonylureas and meglitinides) that may cause hypoglycemia; concomitant administration of medications that may lower the seizure threshold, including other bupropion products, antipsychotics, tricyclic antidepressants, theophylline, and systemic steroids.

Clinical experience with bupropion suggests that the risk of seizure may be minimized by adhering to the recommended dosing recommendations, in particular: the total daily dose of CONTRAVE does not exceed 360 mg of the bupropion component (ie, four tablets per day); the daily dose is administered in divided doses (twice daily); the dose is escalated gradually; no more than two tablets are taken at one time; coadministration of CONTRAVE with high-fat meals is avoided; if a dose is missed, a patient should wait until the next scheduled dose to resume the regular dosing schedule.

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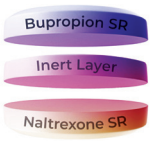
CONTRAVE is an extended-release, fixed-dose combination of naltrexone and bupropion (8 mg/90 mg) to help patients with obesity who struggle with emotional eating[1,2]



Proprietary sustained-release (SR) tri-layer tablet[2]
CONTRAVE is the only FDA-approved drug containing SR forms of naltrexone and bupropion indicated for weight loss

CONTRAVE targets 2 areas of the brain to give patients more control over their eating[2]*

Within the mesolimbic reward system, **naltrexone** and **bupropion** regulate feelings of pleasure when eating to help control cravings. In the hypothalamus, naltrexone and bupropion work synergistically to curb hunger.[3,4]

Naltrexone HCl[2,4]	Bupropion HCl
• Opioid receptor antagonist • Decreases food cravings • Indicated for the treatment of alcohol and opioid dependence	• Dopamine and norepinephrine reuptake inhibitor[5] • Stimulates proopiomelanocortin neurons[5] • Decreases smoking cravings[6] • Indicated for the symptomatic relief of major depressive disorder, the prevention of seasonal major depressive episodes, and as an aid to smoking cessation[6]

CONTRAVE is not indicated for the treatment of alcohol or opioid dependence, for the symptomatic relief of major depressive disorder or other psychiatric disorders, or for smoking cessation.[2]

*The exact neurochemical effects of CONTRAVE leading to weight loss are not fully understood.[2]

IMPORTANT SAFETY INFORMATION (CONT'D)

Patients Receiving Opioid Analgesics

Vulnerability to Opioid Overdose: CONTRAVE should not be administered to patients receiving chronic opioids, due to the naltrexone component, which is an opioid receptor antagonist. If chronic opiate therapy is required, CONTRAVE treatment should be stopped. In patients requiring intermittent opiate treatment, CONTRAVE therapy should be temporarily discontinued and lower doses of opioids may be needed. Patients should be alerted that they may be more sensitive to opioids, even at lower doses, after CONTRAVE treatment is discontinued. An attempt by a patient to overcome any naltrexone opioid blockade by administering large amounts of exogenous opioids is especially dangerous and may lead to a fatal overdose or life-threatening opioid intoxication (e.g., respiratory arrest, circulatory collapse). Patients should be told of the serious consequences of trying to overcome the opioid blockade.

Precipitated Opioid Withdrawal: An opioid-free interval of a minimum of 7 to 10 days is recommended for patients previously dependent on short-acting opioids, and those patients transitioning from buprenorphine or methadone may need as long as two weeks. Patients should be made aware of the risks associated with precipitated withdrawal and encouraged to give an accurate account of last opioid use.

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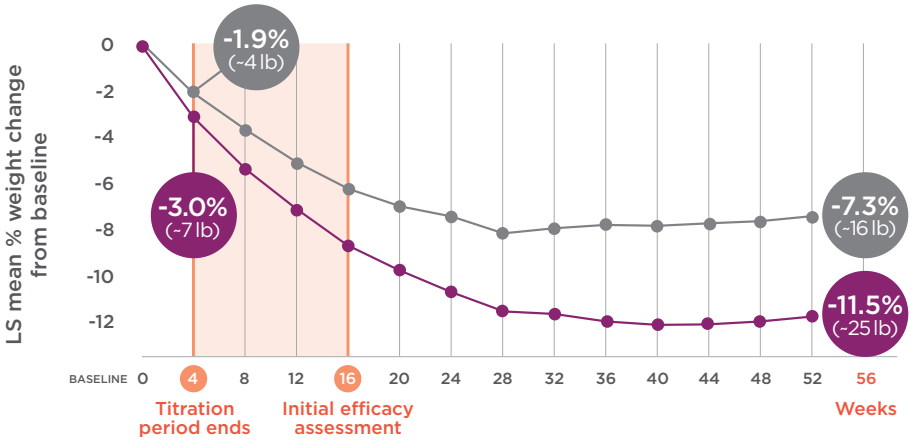
CONTRAVE is proven to help patients lose weight and keep it off[5]

In the COR-BMOD study, patients with obesity participated in 28 group counseling sessions across 56 weeks and received individualized daily caloric goals and a prescribed exercise regimen[2,5]

COR-BMOD: mean percent weight change over 56 weeks in completers[2,5,7]



†Difference from placebo, *P*<0.001.

● CONTRAVE + BMOD (n=301) ● Placebo + BMOD (n=106)

Discontinuation rates of the study drug were similar in the CONTRAVE (42.1%) and placebo (41.6%) groups[2]

ITT-LOCF at 56 weeks: CONTRAVE vs placebo -8.1% (~18 lb),† -4.9% (~11 lb)[2]

Study design: COR-BMOD was a 56-week, multicenter, double-blind, placebo-controlled study. Patients were randomized to receive CONTRAVE 32 mg/360 mg daily or placebo. The coprimary endpoints were percent change from baseline body weight and the proportion of patients achieving a ≥5% reduction in body weight at Week 56. LOCF was used for missing data.[2,5]

Patients met in groups of 10 to 20 people for 90 minutes and received intensive behavioral modification by registered dietitians, behavioral psychologists, or exercise specialists. Group meetings were held weekly for the first 16 weeks, every other week for the next 12 weeks, and monthly thereafter (28 sessions in total).[5]

CONTRAVE ITT: n=565; placebo ITT: n=196. Average baseline parameters were CONTRAVE: 221 lb, 43-in waist circumference; placebo: 224 lb, 43-in waist circumference. Patients who completed 56 weeks of treatment: CONTRAVE: 57.9%; placebo: 58.4%.[2,5]

In another randomized controlled trial (COR-I) with similar average baseline parameters to COR-BMOD, endpoint results over 56 weeks in completers/ITT groups for patients taking CONTRAVE (n=296/538) vs placebo (n=290/536), respectively, were mean weight change from baseline: -8.1%/-5.4% vs -1.8%/-1.3%; patients achieving ≥5% weight loss: 62%/42% vs 23%/17%; and mean change in waist circumference: -2.7 in/-2.4 in vs -1.1 in/-1.0 in.[2,8,9]

BMOD=behavioral modification; ITT=intent to treat; LOCF=last observation carried forward; LS=least squares.

IMPORTANT SAFETY INFORMATION (CONT'D)

Increase in Blood Pressure (BP) and Heart Rate (HR)

CONTRAVE can cause an increase in systolic BP, diastolic BP, and/or resting HR. These events were observed in both patients with and without evidence of preexisting hypertension. In clinical practice with other bupropion-containing products, hypertension, in some cases severe and requiring acute treatment, has been reported. Blood pressure and pulse should be measured prior to starting therapy with CONTRAVE and should be monitored at regular intervals consistent with usual clinical practice, particularly among patients with controlled hypertension prior to treatment.

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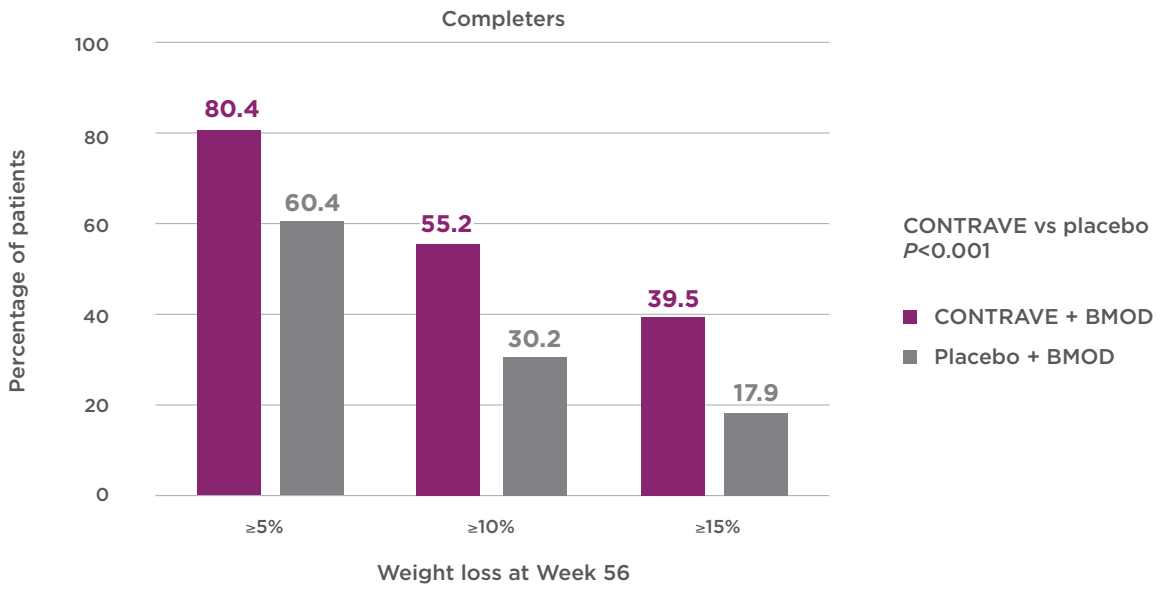
Significantly more patients taking CONTRAVE saw meaningful reductions in body weight[2,5]

More than half of completers (55%) in COR-BMOD achieved ≥10% weight loss



- 57% of patients taking CONTRAVE achieved ≥5% weight loss vs 43% of those taking placebo (ITT-LOCF)[2]
- 35% of patients taking CONTRAVE achieved ≥10% weight loss vs 21% of those taking placebo (ITT-LOCF)[2]

IMPORTANT SAFETY INFORMATION (CONT'D)

Allergic Reactions

Anaphylactoid/anaphylactic reactions and symptoms suggestive of delayed hypersensitivity have been reported with bupropion, as well as rare spontaneous reports of erythema multiforme, Stevens-Johnson syndrome, and anaphylactic shock. Instruct patients to discontinue CONTRAVE and consult a healthcare provider if they develop an allergic or anaphylactoid/anaphylactic reaction (eg, skin rash, pruritus, hives, chest pain, edema, or shortness of breath) during treatment.

Hepatotoxicity

Cases of hepatitis, clinically significant liver dysfunction, and transient asymptomatic hepatic transaminase elevations have been observed with naltrexone exposure. Warn patients of the risk of hepatic injury and advise them to seek medical attention if they experience symptoms of acute hepatitis. Use of CONTRAVE should be discontinued in the event of symptoms and/or signs of acute hepatitis.

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The tolerability of CONTRAVE was demonstrated in thousands of patients[2]

Adverse reactions reported with ≥4% incidence with CONTRAVE and more commonly than placebo[2]		
Adverse reaction	**CONTRAVE (N=2545)**	**Placebo (N=1515)**
Nausea	32.5%	6.7%
Constipation	19.2%	7.2%
Headache	17.6%	10.4%
Vomiting	10.7%	2.9%
Dizziness	9.9%	3.4%
Insomnia	9.2%	5.9%
Dry mouth	8.1%	2.3%
Diarrhea	7.1%	5.2%
Anxiety	4.2%	2.8%
Hot flush	4.2%	1.2%
Fatigue	4.0%	3.4%
Tremor	4.0%	0.7%

- 24% of patients receiving CONTRAVE and 12% of patients receiving placebo discontinued treatment because of an adverse event[2]
- The most frequent adverse reactions leading to discontinuation were nausea (6.3%), headache (1.7%), and vomiting (1.1%)[2]
- Common GI-related adverse events were generally transient in nature and resolved over time (about 2 to 4 weeks)[5,8,10]

IMPORTANT SAFETY INFORMATION (CONT'D)

Activation of Mania

Bupropion, a component of CONTRAVE, is a drug used for the treatment of depression. Antidepressant treatment can precipitate a manic, mixed, or hypomanic episode. The risk appears to be increased in patients with bipolar disorder or who have risk factors for bipolar disorder. Prior to initiating CONTRAVE, screen patients for history of bipolar disorder and the presence of risk factors for bipolar disorder (eg, family history of bipolar disorder, suicide, or depression). CONTRAVE is not approved for use in treating bipolar depression.

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CONTRAVE allows for full titration within 1 month[2]

Standard dosing for CONTRAVE (8 mg/90 mg)[2]*

	Week 1	Week 2	Week 3	Week 4+
AM Tip: take with breakfast	1 pill in AM	1 pill in AM	2 pills in AM	2 pills in AM
PM Tip: take before dinner	N/A	1 pill in PM	1 pill in PM	2 pills in PM

Pills not actual size.

- CONTRAVE is a convenient, oral option in combination with diet and exercise[2]
- Do not administer CONTRAVE with high-fat meals due to increased risk of seizures[2]

*Dose adjustments are needed for patients with moderate, severe, or end-stage renal impairment and hepatic impairment. Maximum recommended daily doses are as follows: moderate or severe renal impairment: 2 pills per day (1 in the AM, 1 in the PM). Moderate hepatic impairment: 2 pills per day (1 in the AM, 1 in the PM).
End-stage renal disease or severe hepatic impairment: not recommended for use in these patients. Concomitant use with CYP2B6 inhibitors: 2 pills per day (1 in the AM, 1 in the PM).[2]

IMPORTANT SAFETY INFORMATION (CONT'D)

Angle-Closure Glaucoma

The pupillary dilation that occurs following use of many antidepressant drugs, including bupropion, may trigger an angle-closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy.

Hypoglycemia with Use of Antidiabetic Medications

Weight loss may increase the risk of hypoglycemia in patients with type 2 diabetes mellitus treated with insulin and/or insulin secretagogues (eg, sulfonylureas). Measurement of blood glucose levels prior to starting CONTRAVE and during CONTRAVE treatment is recommended in patients with type 2 diabetes. Decreases in medication doses for antidiabetic medications that are non-glucose-dependent should be considered to mitigate the risk of hypoglycemia.

Adverse Reactions

Most common adverse reactions (≥5%) include: nausea (32.5%), constipation (19.2%), headache (17.6%), vomiting (10.7%), dizziness (9.9%), insomnia (9.2%), dry mouth (8.1%), and diarrhea (7.1%).

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Patients pay $99† or less for CONTRAVE plus free shipping‡

There are many advantages to enrolling in the CurAccess™ program

Convenient

Quick

Private

Free shipping‡

Instant Fill assistance

May help to stay on treatment plan

†The price of CONTRAVE is $99 per month with free shipping through the CurAccess program. If your insurance covers CONTRAVE, it may cost less. The CurAccess program is offered by our partner pharmacies. Subject to patient eligibility.

Patients who participate in federal programs such as Medicaid, Medicare Part D, and TRICARE are eligible for the program. To receive benefits from the CurAccess program, the prescription will be processed with the assumption that the participant is a cash-paying customer. Please see Terms and Conditions at sign-up for eligibility.

‡Home delivery is offered by a third-party partner.

As part of the CurAccess program, Instant Fill works with pharmacy partners to streamline the process and help patients get their medication quickly

- CurAccess pharmacies will collect and check insurance coverage for all CONTRAVE claims
- CurAccess pharmacies will assist in prior authorization (PA) submission for claims rejected due to PA requirement
- Depending on initial claim status, the prescription will be shipped to the patient at the lowest cost possible
- If the claim is initially denied, the patient will pay just $99 for CONTRAVE
- If the claim is ultimately approved at a lower cost, patients will be refunded the difference from the $99 price

Don't let your patients pay more than $99. Enroll them in CurAccess today.

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When it comes to treating obesity, one size does not fit all.

Consider CONTRAVE for those patients struggling with emotional eating[1]

IMPORTANT SAFETY INFORMATION (CONT'D)

Drug Interactions

Use caution and consider dose reduction of drugs metabolized by CYP2D6 when using with CONTRAVE. Avoid concomitant use with MAOIs and CYP2B6 inducers. Reduce CONTRAVE dose when taken with CYP2B6 inhibitors. Dose CONTRAVE with caution when used with drugs that lower seizure threshold. Use caution and monitor for CNS toxicity when using CONTRAVE concomitantly with dopaminergic drugs (levodopa and amantadine). CONTRAVE can cause false positive urine test results for amphetamines.

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References: 1. Acosta A, Camilleri M, Dayyeh, BA, et al. Selection of antiobesity medications based on phenotypes enhances weight loss: a pragmatic trial in an obesity clinic. *Obesity (Silver Spring)*. 2021;29(4)29:662-671. doi:10.1002/oby.23120 **2.** CONTRAVE (naltrexone HCl and bupropion HCl) [prescribing information]. Brentwood, TN: Currax Pharmaceuticals LLC; 2021. **3.** Greenway FL. Physiological adaptations to weight loss and factors favouring weight regain. *Int J Obes (Lond)*. 2015;39(8):1188-1196. doi:10.1038/ijo.2015.59 **4.** Hollander P, Gupta AK, Plodkowski R, et al. Effects of naltrexone sustained-release/bupropion sustained-release combination therapy on body weight and glycemic parameters in overweight and obese patients with type 2 diabetes. *Diabetes Care*. 2013;36(12):4022-4029. doi:10.2337/dc13-0234 **5.** Wadden TA, Foreyt JP, Foster GD, et al. Weight loss with naltrexone SR/bupropion SR combination therapy as an adjunct to behavior modification: the COR-BMOD trial. *Obesity (Silver Spring)*. 2011;19(1):110-120. doi:10.1038/oby.2010.147 **6.** PDR Search. Bupropion hydrochloride - Drug Summary. Accessed February 10, 2022. https://www.pdr.net/drug-summary/Wellbutrin-SR-bupropion-hydrochloride-238#topPage **7.** Data on file. Currax Pharmaceuticals LLC. Brentwood, TN; 2010. **8.** Greenway FL, Fujioka K, Plodkowski RA, et al. Effect of naltrexone plus bupropion on weight loss in overweight and obese adults (COR-I): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2010;376(9741):595-605. doi:10.1016/S0140-6736(10)60888-4 **9.** Data on file. Currax Pharmaceuticals LLC. Brentwood, TN; 2019. **10.** Hong K, Herrmann K, Dybala C, Halseth AE, Lam H, Foreyt JP. Naltrexone/bupropion extended release-induced weight loss is independent of nausea in subjects without diabetes. *Clin Obes*. 2016;6(5):305-312. doi:10.1111/cob.12157

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