Direct Healthcare Professional Communication (DHPC)

May 15, 2026

Contrave (naltrexone/bupropion): long-term cardiovascular risk and new recommendations on annual assessment

Dear Healthcare Professional,

Algorithm In agreement with the Saudi Food and Drug Authority (SFDA), would like to inform you of the following:

Summary

- **The cardiovascular risks of Contrave in patients treated for longer than one year have not been fully determined.**
- **Treatment with Contrave should be discontinued after one year if a patient has not maintained a loss of at least 5% of their initial body weight when starting treatment with Contrave.**
- **Physicians should conduct an annual assessment when considering treatment continuation, to ensure no adverse change in cardiovascular risk and maintenance of weight loss.**

Background on the safety concern

Contrave contains a fixed-dose combination of naltrexone hydrochloride and bupropion hydrochloride. It is indicated, as an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (≥18 years) with an initial body mass index (BMI) of ≥ 30 kg/m^2 (obese), or ≥ 27 kg/m^2 to < 30 kg/m^2 (overweight) in the presence of one or more weight-related comorbidities (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension). Treatment with Contrave should be discontinued after 16 weeks if patients have not lost at least 5% of their initial body weight. The need for continued treatment should be re-evaluated annually.

Uncertainties regarding long-term cardiovascular risks were noted at the time of Contrave's initial marketing authorisation in 2015. Studies conducted to date have demonstrated cardiovascular safety and a positive benefit-risk balance for Contrave treatment lasting up to 12 months. The conduct of a study to further investigate the long-term cardiovascular safety was imposed as a condition of the marketing authorisation. However, long- term study data has not been generated to date.

Ongoing concerns about potential long-term cardiovascular risks, along with the absence of a sufficient study plan to address this uncertainty in a timely manner, led to a review of the benefit–risk balance of Contrave. The review confirmed that the data available so far was insufficient to fully determine cardiovascular safety beyond 12 months. As a result, further measures have been implemented to minimise the potential risk for cardiovascular events with long-term use of Contrave. Treatment with Contrave should be discontinued after one year if a patient has not maintained a loss of at least 5% of their initial body weight. Further, when annually assessing the treatment continuation, healthcare professionals should monitor the absence of adverse change in patients' cardiovascular risk and maintenance of weight loss of at least 5% of their initial body weight.

This assessment should be conducted in discussion with the patient.

Call for reporting

Healthcare professionals are asked to report any suspected adverse drug reactions associated with the use of Contrave in accordance with the national spontaneous reporting system

Contact Information:	Contact Information:
Pharmacovigilance department at Algorithm:	**The National Pharmacovigilance Centre (NPC- Saudi Food and Drug Authority (SFDA)):**
Email: Pharmacovigilance-AL@algorithm-lb.com	
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Website: www.algorithm-lb.com	Website: ade.sfda.gov.sa

Scan the code below for website access.

Contrave is subject to additional monitoring, meaning that it is monitored even more intensively than other medicines.

Company contact point

For further information or medical inquiries, healthcare professionals may contact Algorithm medical information department at medinfo@algorithm-lb.com

Safety Information & AE Reporting

Healthcare professionals are advised to carefully review this material in full prior to use.
Please refer to the SPC/PIL for further details and ensure that any adverse events are reported to the SFDA.

This document has been approved by the Executive Directorate of Pharmacovigilance at the SFDA.

Thank you,

Joumana Jaber

Regulatory, Medical and External Affairs Lead

Joumana Jaber

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[1] NCT06098079; Available at: https://clinicaltrials.gov/study/NCT06098079