Direct Healthcare Professional Communication

April 2025

Important information on Risks associated with the simultaneous use of Naltrexone hydrochloride / bupropion hydrochloride and opioids

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance (PVGA) at the Egyptian drug authority (EDA) would like to inform you **about Risks associated with the simultaneous use of Naltrexone hydrochloride / bupropion hydrochloride and opioids**

Summary

- Naltrexone hydrochloride / bupropion hydrochloride is approved as an adjunct to a calorie-restricted diet and increased physical activity for weight management in adult patients (≥18 years) with an initial body mass index (BMI) of:
  - ≥30 kg/m2 (obese), or
  - ≥ 27 kg/m2 to < 30 kg/m2 (overweight) with at least one weight-related concomitant disease (e.g. type 2 diabetes, dyslipidemia or controlled hypertension)

- Treatment with Naltrexone hydrochloride / bupropion hydrochloride should be discontinued after 16 weeks if patients have not reduced their initial weight by at least 5% at that time

Background on the safety concern

- Naltrexone hydrochloride / bupropion hydrochloride, a weight loss medicine, is known to block the action of opioid medicines (including painkillers such as morphine and codeine, other opioids used during surgery, and certain medicines for cough, cold or diarrhea).

- This may result in insufficient action of opioid medicines used for anesthesia and pain management during and after surgery

- Inadequate effects of opioids in the context of anesthesia and intra- or postoperative analgesia have been described in case reports and in the literature in patients treated with Naltrexone hydrochloride / bupropion hydrochloride.

- Rare but serious side effects such as seizures and Serotonin syndrome (a potentially life-threatening condition resulting from too much serotonin in the body) has also been reported in patients taking Naltrexone hydrochloride / bupropion hydrochloride and opioids.

- Due to the risk of these side effects, Naltrexone hydrochloride / bupropion hydrochloride must not be used in patients receiving opioid treatment, in patients who are dependent on opioids or are receiving an opioid substitute such as methadone, and in patients undergoing acute opioid withdrawal.

- If opioid use is suspected, a test should be performed to ensure clearance of opioid containing medicines before starting treatment with Naltrexone hydrochloride / bupropion hydrochloride.

- Patients should be cautioned against the concomitant use of opioids during treatment with Naltrexone hydrochloride / bupropion hydrochloride. If opioids are required (e.g. due to elective surgery), Naltrexone hydrochloride / bupropion hydrochloride should be discontinued at least three days before opioid treatment is started.

- In the event of emergency surgery, there is a risk that the effect of opioids may be reduced in patients who may be treated with Naltrexone hydrochloride / bupropion hydrochloride

Further Information

Following a review of the safety of Naltrexone hydrochloride / bupropion hydrochloride (naltrexone/bupropion), a medicine used to reduce weight, EDA recommends strengthening advice to minimize the risks of interactions between Naltrexone hydrochloride / bupropion hydrochloride and opioid medicines (including painkillers such as morphine and codeine, other opioids used in surgery and certain medicines for cough, cold or diarrhea).

In particular, the EDA points out that opioid painkillers may not be sufficiently effective in patients taking Naltrexone hydrochloride / bupropion hydrochloride because one of the active substances in Naltrexone hydrochloride / bupropion hydrochloride, naltrexone, blocks the action of opioids. Therefore, if a patient needs treatment with opioids while taking Naltrexone hydrochloride / bupropion hydrochloride, for example because of a planned operation, they should stop taking Naltrexone hydrochloride / bupropion hydrochloride for at least three days before starting treatment with opioid medicines.

In addition, the EDA informs patients and healthcare professionals about the risk of rare but serious and potentially life-threatening reactions such as seizures and serotonin syndrome (a potentially life-threatening condition caused by too high levels of serotonin in the body) in people taking Naltrexone hydrochloride / bupropion hydrochloride with opioids.

To minimize these risks, the EDA recommends that Naltrexone hydrochloride / bupropion hydrochloride should not be used in people receiving treatment with opioids.

Reference

BASG:
https://www.basg.gv.at/fileadmin/redakteure/06_Gesundheitsberufe/DHPC/2024/240909_Mysimba.pdf

Call for reporting
Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://vigiflow-eforms.who-umc.org/eg/med
QR Code:

PO Box: 11451

Hotline: 15301