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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

29 July 2024

Dear Healthcare Professionals,

EMA advises about risks of using weight loss medicine Mysimba with opioids

Your attention is drawn to the European Medicines Agency (EMA)'s announcement that following a routine review of the safety of the weight loss medicine Mysimba (naltrexone/bupropion), EMA recommends strengthening existing advice to minimise the risks from interactions between Mysimba and opioid-containing medicines (including painkillers such as morphine and codeine, other opioids used during surgery, and certain medicines for cough, cold or diarrhoea).

In particular, EMA is advising that opioid painkillers may not work effectively in patients taking Mysimba, because one of the active substances in Mysimba, naltrexone, blocks the effects of opioids. If a patient requires opioid treatment while taking Mysimba, for example due to a planned surgery, they should therefore stop taking Mysimba for at least three days before treatment with opioid medicines starts.

Furthermore, EMA is informing 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 that results from having too much serotonin in the body), in people taking Mysimba with opioids.

To minimise these risks, EMA recommends that Mysimba must not be used in people receiving treatment with opioid medicines. This is in addition to the existing contraindications

stating that Mysimba must not be used in people who are dependent on long-term opioids, people receiving treatment with opioid agonist such as methadone, and people going through opioid withdrawal.

Advice for healthcare professionals:

- Insufficient effects of opioids as part of anaesthesia and intra- or post-operative analgesia have been described in case reports and the literature in patients treated with Mysimba.
- Furthermore, rare but serious and potentially life-threatening reactions such as seizures and serotonin syndrome have been observed after co-administration of Mysimba and opioids.
- Mysimba must not be used in patients receiving opioid-containing medicines, patients currently dependent on opioids, patients treated with opioid agonists used in opioid dependence (e.g. methadone) or in patients in acute opioid withdrawal. If opioid use is suspected, a test should be performed to ensure clearance of opioid medication before starting treatment with Mysimba.
- Patients should be warned against the concomitant use of opioids during treatment with Mysimba. If opioid use is required (e.g. due to a planned surgery), Mysimba should be stopped for a minimum of three days before starting opioid treatment.
- In case of emergency surgery in patients potentially treated with Mysimba, there is a risk that the effects of opioids may be reduced.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/ema-advises-about-risks-using-weight-loss-medicine-mysimba-opioids

In Hong Kong, Mysimba is a registered pharmaceutical product under the name Contrave Prolonged-release Tablets 8mg/90mg (HK-66934), a prescription-only medicine and is the only registered pharmaceutical product containing naltrexone and bupropion. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to naltrexone and combination product of naltrexone with bupropion. The DH has received 4 cases of adverse drug reactions with bupropion but these cases were not related to concomitant use of bupropion with opioids. In light of the above EMA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html . You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Terence MAN)
for Assistant Director (Drug)