Agenzia Italiana del Farmaco

AIFA

Ufficio di Farmacovigilanza

A tutti i Titolari AIC di Medicinali a base di Oppioidi, di Benzodiazepine e derivati

OGGETTO: Richiesta di modifica stampati dei medicinale a base di Oppioidi, di Benzodiazepine e derivati in accordo a quanto pubblicato nel sito del CMDh nella sezione "Advice from CMDh".

Si richiede alle Aziende in indirizzo, di aggiornare gli stampati di tutti i medicinali coinvolti dal comunicato di cui all'oggetto, disponibile al seguente link:

http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Advice_from_CMDh/CMDh_372_2018_Rev0_02_2018.pdf

A tal fine, i titolari di AIC coinvolti dovranno presentare una domanda di variazione per modifica stampati di tipo IB, categoria C.I.z in quanto non è stata resa disponibile una traduzione armonizzata dei testi, all'Ufficio PPA dell'AIFA entro e non oltre 60 giorni dalla data di pubblicazione sul sito del CMDh.

Si riportano di seguito i testi proposti dal CMDh, che costituiscono i "key messages" da considerare nella modifica stampati:

Proposed text for benzodiazepines and related drugs
SmPC section 4.4: Special warnings and precaution for use
Risk from concomitant use of opioids:
Concomitant use of <product name> and opioids may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing of sedative medicines such as benzodiazepines or related drugs such as <Product name> with opioids should be reserved for patients Concomitant use of benzodiazepines/benzodiazepine like products and opioids for whom alternative treatment options are not possible. If a decision is made to prescribe <Product name> concomitantly with opioids, the lowest effective dose should be used, and the duration of treatment should be as short as possible (see also general dose recommendation in section 4.2).
The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers (where applicable) to be aware of these symptoms (see section 4.5).

SmPC section 4.5: Interaction with other medicinal products

Opioids:
The concomitant use of sedative medicines such as benzodiazepines or related drugs such as <Product name> with opioids increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dosage and duration of concomitant use should be limited (see section 4.4).

PL (section 2), Other medicines and <Product name>:
Concomitant use of <Product name> and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe <Product name> together with opioids the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Proposed text for opioids
SmPC section 4.4: Special warnings and precaution for use
Risk from concomitant use of sedative medicines such as benzodiazepines or related drugs:
Concomitant use of <product name> and sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedative medicines should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe <Product name> concomitantly with sedative medicines, the lowest effective dose should be used, and the duration of treatment should be as short as possible.

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms (see section 4.5).

SmPC section 4.5: Interaction with other medicinal products Sedative medicines such as benzodiazepines or related drugs:
he concomitant use of opioids with sedative medicines such as benzodiazepines or related drugs increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited (see section 4.4). Concomitant use of benzodiazepines/benzodiazepine like products and opioids

PL (section 2), Other medicines and <Product name>:
Concomitant use of <Product name> and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe <Product name> together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Nella domanda di variazione dovrà essere precisato che la richiesta proviene dall'Ufficio di Farmacovigilanza.

Come riportato nel comunicato, " If the message is already covered in the product information, in a similar wording, there is no need to submit additional variations. […] (The proposed text is not seen as applicable for products intended for an emergency setting.)"