Bundesamt für Sicherheit
im Gesundheitswesen

BASG / AGES
Institut LCM
Traisengasse 5, A-1200 Wien

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Kontakt: Ing. Veronika Heimlich, B.Sc.
Abteilung: REGA
Tel. / Fax: +43 (0) 505 55 – 36247
E-Mail: pv-implementation@ages.at
Unser Zeichen: PHV-10749559-A-180314-EUIM
Ihr Zeichen:

PHV-issue: Opioide

Sehr geehrte Damen und Herren,

Das CMDh kam zu dem Schluss, dass in den Produktinformationen von Opioiden folgende Informationen (siehe Anhang) sinngemäß enthalten sein müssen. (Siehe auch CMDh Press release held on 19-22 February 2018: http://www.hma.eu/249.html)

Auszug aus dem CMDh Press release (Report from the CMDh meeting held on 19-22 February 2018)

Concomitant use of benzodiazepines/benzodiazepine like products and opioids

In August 2016, the FDA decided to add warnings to the drug labelling of prescription opioids (indicated for pain or cough) and benzodiazepines [https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm518110.htm]. It concerns the serious risks of respiratory depression, coma and death, associated with the combined use of certain opioids and benzodiazepines. Separate wording has been proposed for opioids for pain, substitution therapy or cough and for benzodiazepines.

Following this, national competent authorities have received corresponding variations for national approved products in the EEA.

With the aim of having harmonised texts within the EEA, CMDh has agreed on a proposed text to be included for benzodiazepines and benzodiazepine like products (i.e. z-drugs), with regards to the warnings for concomitant use with opioids. A corresponding text for opioids was also agreed.

The proposed text is guidance on key messages that should be included, taking into account any necessary adaptation to the current product information of the individual product.

Variations according to the proposed text should be submitted as Type IB under category C.I.z as no harmonised national translations are available in all concerned member states.

If the message is already covered in the product information of concerned products, with a similar wording, there is no need to submit additional variations.

The proposed text for benzodiazepines and benzodiazepine like products and a corresponding text for opioids will be published on the CMDh website under “Advice from CMDh”.

Auszug aus dem Advice from CMDh

Concomitant use of benzodiazepines/benzodiazepine like products and opioids

Introduction

In August 2016 the FDA decided to add warnings to the drug labelling of prescription opioids (indicated for pain or cough) and benzodiazepines. It concerns the serious risks of respiratory depression, coma and death, associated with the combined use of certain opioids and benzodiazepines. Separate wording has been proposed for opioids for pain, substitution therapy or cough and for benzodiazepines.
Following this, National Competent Authorities have received corresponding variations for National approved products in the EEA.

With the aim of having harmonised texts within the EEA, CMDh has agreed on a proposed text to be included for benzodiazepines and benzodiazepine like products (i.e. z-drugs), with regards to the warnings for concomitant use with opioids. A corresponding text for opioids is also agreed.

The proposed text is **guidance on key messages** that should be included, taking into account any necessary adaptation to the current product information of the individual product.

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 for benzodiazepines and benzodiazepine like products is given below, followed by a corresponding text for opioids.

(The proposed text is not seen as applicable for products intended for an emergency setting.)

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:

The 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).

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.