Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Unternehmen/Frau/Herr
Organisationseinheit (optional)
(z. H.) Vorname Nachname
Straße
PLZ Ort

Datum: 08.11.2024
Kontakt: Ing. Veronika Heimlich BSc
Tel: +43 50555 36247
E-Mail: pv-implementation@basg.gv.at
Unser Zeichen: PHV-103673981-A-241108
Ihr Zeichen:

PHV-issue: Quinolone- and Fluoroquinolone containing medicinal products for systemic and inhalation use

Sehr geehrte Damen und Herren,
Aufgrund eines Outcomes of PSUSA follow-up via variation (PSUFU), dessen Ergebnis durch das CMDh bestätigt wurde,kommt es zu der Änderung der Genehmigungen für das Inverkehrbringen der Arzneimittel mit den Wirkstoffen Ciprofloxacin; Delafloxacin; Levofloxacin; Lomefloxacin; Moxifloxacin; Norfloxacin; Ofloxacin; Pefloxacin; Prulifloxacin; Rufloxacin.

(siehe: http://www.hma.eu/611.html)

Die Zulassungsinhaber werden aufgefordert, bis spätestens 7.1.2025 eine Variation gemäß "Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures." beim Institut LCM einzureichen.

Betroffene Arzneispezialitäten:
-xxx

Bei Unklarheiten bezüglich der Implementierung oder wenn die Änderungen bereits aufgenommen worden sind, kontaktieren Sie uns bitte per E-Mail (pv-implementation@basg.gv.at).

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In der Begründung ist „**PHV-Issue: „Quinolone- and Fluoroquinolone containing medicinal products for systemic and inhalation use -CZ/H/PSUFU/A31/1452/202210**" sowie die **Geschäftszahl (PHV-103673981-A-241108)** anzugeben.

Mit freundlichen Grüßen
Für das Bundesamt

Ing. Veronika Heimlich BSc

Auszug aus dem Final Lead Member State PSUR Follow-Up assessment report for Quinolone- and fluoroquinolonecontaining medicinal products for systemic and inhalation use

3. Recommendations

Based on the review of data submitted, the LMS considers that the product information should be updated as follows:

Update of the existing information under the description of selected adverse drug reactions in section 4.8 of the SmPC to add new aspects of prolonged, disabling and potentially irreversible adverse drug reactions. The Package leaflet is updated accordingly.

The following changes to the product information of medicinal products containing fluoroquinolone for systemic or inhalation use are recommended (new text **underlined and in bold**, deleted text ~~strike through~~):

Summary of Product Characteristics

- Section 4.8

The existing information under the description of selected adverse drug reactions regarding *prolonged, disabling and potentially irreversible adverse drug reactions* should be revised as follows:

*Very rare cases of prolonged (up to months or years), disabling and potentially irreversible serious drug reactions affecting several, sometimes multiple, system organ classes and senses (including reactions such as tendonitis, tendon rupture, arthralgia, pain in extremities, gait disturbance, neuropathies associated with paraesthesia **and neuralgia**, ~~depression,~~ fatigue, **psychiatric symptoms (including sleep disorders, anxiety, panic attacks, depression and suicidal ideation),** memory **and concentration** impairment, ~~sleep disorders,~~ and impairment of hearing, vision, taste and smell) have been reported in association with the use of quinolones and fluoroquinolones in some cases irrespective of pre-existing risk factors (see Section 4.4).

Package Leaflet

Section 4

Information regarding *prolonged, disabling and potentially irreversible adverse drug reactions* should be revised as follows:

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), ~~depression,~~ fatigue, ~~sleep disorders,~~ memory **and concentration** impairment, **mental health effects (which may include sleep disorders, anxiety, panic attacks, depression and suicidal ideation),** as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Heimlich Veronika
am 8.11.2024

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