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Ihr Zeichen:

PHV-issue: Eisensulfat-hältige Tabletten

Sehr geehrte Damen und Herren,

Das CMDh kam zu dem Schluss, dass in den Produktinformationen von Eisensulfat-hältigen Tabletten folgende Informationen (siehe Anhang) sinngemäß enthalten sein müssen. (Siehe auch CMDh Press release held on 23-25 April 2018: <http://www.hma.eu/249.html>)

Auszug aus dem CMDh Press release

(Report from the CMDh meeting held on 23-25 April 2018)

Ferrous sulphate-containing tablets

Following recently submitted variations to update the product information of medicinal products containing ferrous sulphate as active substance, the CMDh noted that the provided information on risk of necrosis of the bronchial mucosa following aspiration of the tablet is not harmonised across EU/EEA Member States. The CMDh has therefore agreed a harmonised wording to be included in section 4.4 and 4.8 of the SmPC and the corresponding text for the package leaflet of concerned products.

Variations to implement 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.

The agreed text for ferrous sulphate-containing tablets will be published on the CMDh website under "Advice from CMDh".

Auszug aus dem Advice from CMDh

Harmonised warning for ferrous sulphate-containing tablets on dysphagia and related bronchostenosis due to risk of aspiration

SmPC

Section 4.4:

Aspiration of iron sulfate tablets can cause necrosis of the bronchial mucosa which may result in coughing, haemoptysis, bronchostenosis and/or pulmonary infection (even if aspiration happened days to months before these symptoms occurred). Elderly patients and patients who have difficulties swallowing should only be treated with iron sulfate tablets after a careful evaluation of the individual patient's risk of aspiration. Alternative formulations should be considered. Patients should seek medical attention in case of suspected aspiration.

Section 4.8:

Bronchial stenosis (see section 4.4)

PL

Warnings and precautions

Talk to your doctor before you take X if you:

Have difficulties swallowing

If you accidentally choke on a tablet, please contact your doctor as soon as possible. This is because there is a risk of ulcers and narrowing of the bronchus occurring if the tablet enters the airways. This may result in persistent coughing, coughing up blood and/or feeling out of breath, even if the choking happened days to months before these symptoms occurred. Therefore you need to be urgently assessed to make sure that the tablet doesn't damage your airways.

Potential side effects

All patients, but especially elderly patients and patients with difficulties swallowing may also be at risk of ulceration of the throat or the esophagus (the tube that connects your mouth with your stomach). If the tablet enters the airways, there may be a risk of ulceration of the bronchus (the major air passages of the lungs), resulting in bronchial narrowing.