Harmonised warning for ferrous sulfate-containing medicinal products on dysphagia and related bronchostenosis due to risk of aspiration
Advice from CMDh

**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

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1 Applicable to all medicinal products within ATC B03A A07 “ferrous sulfate”, except oral liquids
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.