



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 4-8 July 2016 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found [here](#) (in English only).

1. Ferrous sulfate – Mouth ulceration (EPITT no 18623)

Summary of product characteristics

4.2. Posology and method of administration

Method of administration:

The tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water.

Tablets should be taken before meals or during meals, depending on gastrointestinal tolerance.

4.4. Special warnings and precautions for use

Due to the risk of mouth ulcerations and tooth discolouration, tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water.

4.8. Undesirable effects

Post-marketing: The following ADRs have been reported during post-marketing surveillance. The frequency of these reactions is considered not known (cannot be estimated from the available data).

Gastrointestinal disorders:

mouth ulceration*

* in the context of incorrect administration, when the tablets are chewed, sucked or kept in mouth.

Elderly patients and patients with deglutition disorders may also be at risk of oesophageal lesions or of bronchial necrosis, in case of false route.



Package leaflet

2 - What you need to know before you take [Product name]

Warnings and precautions

Due to the risk of mouth ulceration and tooth discolouration, tablets should not be sucked, chewed or kept in the mouth but swallowed whole with water. If you cannot follow this instruction or have difficulty swallowing, please contact your doctor.

3 - How to take [Product name]

Swallow the tablet whole with water. Do not suck, chew or keep the tablet in your mouth.

4 - Possible side effects

Not known (frequency cannot be estimated from the available data)

Mouth ulceration (in case of incorrect use, when tablets are chewed, sucked or left in the mouth)

Elderly patients and patients with difficulty swallowing may also be at risk of ulceration of the throat, oesophagus (the tube that connects your mouth with your stomach) or bronchus (the major air passages of the lungs) if the tablet enters the airways.

2. Proton pump inhibitors (PPIs): dexlansoprazole; esomeprazole; lansoprazole; omeprazole; pantoprazole; rabeprazole – Elevated circulating levels of Chromogranin A (EPITT no 18614)

Summary of product characteristics

4.4. Special warnings and precautions for use

Interference with laboratory tests

Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, [Product name] treatment should be stopped for at least 5 days before CgA measurements (see section 5.1). If CgA and gastrin levels have not returned to reference range after initial measurement, measurements should be repeated 14 days after cessation of proton pump inhibitor treatment.

5.1. Pharmacodynamic properties

During treatment with antisecretory medicinal products, serum gastrin increases in response to the decreased acid secretion. Also CgA increases due to decreased gastric acidity. The increased CgA level may interfere with investigations for neuroendocrine tumours.

Available published evidence suggests that proton pump inhibitors should be discontinued between 5 days and 2 weeks prior to CgA measurements. This is to allow CgA levels that might be spuriously elevated following PPI treatment to return to reference range.

Package leaflet

2 - What you need to know before you take [Product name]

Warnings and precautions

Tell your doctor before taking this medicine, if:

- [...]
- You are due to have a specific blood test (Chromogranin A)