23 November 2026[1]
EMA/PRAC/237907/2026
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 26-29 October 2026 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 on the webpage for PRAC recommendations on safety signals (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

1. Cefpodoxime – Drug interaction between cefpodoxime and proton pump inhibitor resulting in a potentially reduced efficacy of cefpodoxime (EPITT no 20280)

Taking into account the already existing wording in some nationally authorised products, the text may need to be adapted by marketing authorisation holders to individual products.

Summary of product characteristics

4.5 – Interaction with other medicinal products and other forms of interaction

Paragraph to be included under the current text on antacids/H2 blockers

Proton pump inhibitors (PPIs) cause sustained suppression of gastric acid secretion and may therefore reduce the absorption and bioavailability of cefpodoxime. The magnitude and clinical relevance of this potential interaction have not been established.

Package leaflet

2 What you need to know before you use <product name>

[1] Expected publication date. The actual publication date can be checked on the webpage dedicated to PRAC recommendations on safety signals.

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Taking <product name> with other medicines

Tell your doctor or pharmacist if you are taking proton pump inhibitors (medicines used to reduce stomach acid), as these medicines may reduce the absorption of cefpodoxime.