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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 14-17 January 2019 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).

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

1. Biotin – Interference with clinical laboratory tests (EPITT no 19156)

For medicinal products for oral use containing ≥ 150 microgram biotin per dose unit and medicinal products for parenteral use containing ≥ 60 microgram biotin per dose unit

Summary of product characteristics

4.4. Special warnings and precautions for use

Interference with clinical laboratory tests

Biotin may interfere with laboratory tests that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results, depending on the assay. The risk of interference is higher in children and patients with renal impairment and increases with higher doses. When interpreting results of laboratory tests, possible biotin interference has to be taken into consideration, especially if a lack of coherence with the clinical presentation is observed (e.g. thyroid test results mimicking Graves' disease in asymptomatic patients taking biotin or false negative troponin test results in patients with myocardial infarction taking biotin). Alternative tests not susceptible to biotin interference should be used, if available, in cases where interference is suspected. The laboratory personnel should be consulted when ordering laboratory tests in patients taking biotin.

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

Package leaflet

2. What you need to know before you take X

Warnings and precautions

[Product name] contains <quantity> biotin per <dose unit>. If you are about to undergo laboratory testing you must tell your doctor or the laboratory personnel that you are taking or have recently taken [Product name], because biotin may affect results of such tests. Depending on the test, the results may be falsely elevated or falsely low due to biotin. Your doctor may ask you to stop taking [Product name] before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin and affect the results of laboratory tests. Please inform your doctor or the laboratory personnel, if you are taking such products.

2. Gabapentin – Dysphagia (EPITT no 19296)

Summary of product characteristics

4.8. Undesirable effects

Gastrointestinal disorders

Uncommon: dysphagia

Package leaflet

4. Possible side effects

Uncommon: may affect up to 1 in 100 people

- Difficulty swallowing