Biotin in food supplements can influence laboratory test results

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Biotin is a water soluble vitamin that is also known as Vitamin B7 and Vitamin H. It occurs naturally in many foodstuffs. In the human body, biotin is involved in protein, fat and carbohydrate metabolism. Apart from being used in various medicinal products for the prevention and/or treatment of a biotin deficiency, it is also found in numerous food supplements. Among other things, the vitamin is understood to contribute to the maintenance of normal functions of human metabolism and the nervous system, as well as to promote the maintenance of skin, hair and nails.

Specific laboratory tests – so-called immunoassays – make use of biotin's interaction with the protein streptavidin to detect the amount of specific molecules. An example is the determination of the heart-specific protein troponin, which appears in blood in higher amounts when a person has suffered a heart attack. Certain biotinylated reagents, for example antibodies that are directed against troponin and to which biotin has been coupled, can assist in detecting troponin. If streptavidin is anchored at a fixed location in the test system, biotinylated reagents can be "fished out" during the test by binding of the biotin moiety to streptavidin.

If a person uses medication or food supplements containing biotin, a higher amount of free (uncoupled) biotin may be found in the sample to be tested.. This free biotin competes with the biotin proportion of the biotinylated test reagents for biotin binding sites on streptavidin. This can distort test results. For certain test set-ups, it may appear at the end of the test that there is less of the substance to be detected in the sample than is actually the case – possibly leading to a false negative test outcome. In other test variations, the free biotin may lead to false positives – i.e. to the assumption that there is more of a particular substance in the sample. This can also lead to false diagnoses.

A false result from laboratory tests, for example regarding heart-specific troponin, could mean that an inaccurate diagnosis is made, as to whether a heart attack has taken place or not - or that a heart attack is identified too late.

Such laboratory tests employing biotinylated reagents are used to measure a variety of other molecules (e.g. heart, tumour, or infection markers, hormones, HIV, etc.). It is unclear which biotin dose might be sufficient to lead to above-mentioned distorting effects, as the extent of such effects is influenced by the interplay of a number of different factors. Laboratory tests, however, in which biotin plays no functional role, are not affected.

On the grounds of this issue, the European Medicines Agency (EMA) has initiated a risk assessment process. The Pharmacovigilance Risk Assessment Committee (PRAC) at the institute has recommended that all authorisation holders for biotin-containing medicinal products in the EU should include an explanatory note in their product information. This has become mandatory. In addition, a "Dear Doctor Letter" was used in May 2019 to communicate such risks in Germany. This letter was prepared by the German Federal Institute responsible for the approval of drugs and medicines in Germany (German Federal Institute for Drugs and Medical Devices (BfArM)), together with several manufacturing companies. It is directed at employees in healing professions, i. e. doctors, pharmacists as well as employees in laboratories, and informs them of the situation. Although food supplements are also mentioned in the letter, the focus is on medication.

No medical approval is needed prior to the marketing of food supplements in Germany. Based on their predefined lack of pharmaceutical properties and in line with their designated purpose, food supplements are covered by food regulations rather than drug laws. However, before they are placed on the market for the first time, they must be registered with the German Federal Office for Consumer Protection and Food Safety (BVL). This means, however, that the manufacturers of food supplements containing biotin are not required to send a Dear Doctor Letter or comparable information letter or to adjust the product information for their preparations.

The German Federal Institute for Risk Assessment (BfR) therefore recommends that consumers who use biotin-containing food supplements, as well as advisory and treating employees in healthcare professions, should take into consideration that the biotin contained in food supplements at various doses may also have the same detrimental effect on the above-mentioned laboratory tests.

The European Food Safety Authority (EFSA) recommends daily adequate intake levels of biotin for different age groups. For adults, EFSA recommends a daily intake of 40 µg (micrograms) per day. The recommendations of the German Society for Nutrition (DGE) for an adequate intake of biotin are 30-60 µg per day for adolescents from 15 years on and adults.

In human studies, biotin has so far not been shown to lead to adverse health effects, even at intake levels well above recommended intake reference values, so that the German Federal Institute for Risk Assessment (BfR), based on current scientific knowledge, assumes a low risk of adverse health effects. The BfR has therefore so far abstained from recommending maximum levels for biotin in food supplement products.

Further information on food supplements is available from the BfR website

A-Z index of food supplements:

https://www.bfr.bund.de/en/a-z_index/food_supplements-129789.html

BfR "Opinions app"

1 References

Dear Doctor Letter by BfArM about biotin (in German)
https://www.bfarm.de/SharedDocs/Risikoinformationen/Pharmakovigilanz/DE/RHB/2019/rhb-biotin.pdf?__blob=publicationFile&v=5

Drug Safety Bulletin by BfArM and PEI
Bulletin zur Arzneimittelsicherheit (Ausgabe 4) (in German)
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Bulletin/2018/4-2018.pdf?__blob=publicationFile&v=6

PRAC recommendation by the European Medicines Agency (EMA) regarding biotin
https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-14-17-january-2019-prac-meeting_en.pdf

EFSA Scientific Opinion on Dietary Reference Values for biotin
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3580

German Society for Nutrition (DGE): Biotin – Schätzwerte für eine angemessene Ernährung. (in German)
https://www.dge.de/wissenschaft/referenzwerte/biotin/

BfR proposals on maximum levels for vitamins und minerals in food supplements: Weißenborn A, Bakhiya N, Demuth I, Ehlers A, Ewald M, Niemann B, Richter K, Trefflich I, Ziegenhagen R, Hirsch-Ernst KI, Lampen A (2018). Höchstmengen für Vitamine und Mineralstoffe in Nahrungsergänzungsmitteln. Journal of Consumer Protection and Food Safety 13: 25-39. (in German)
https://link.springer.com/article/10.1007/s00003-017-1140-y

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the Federal Government and Federal Laender on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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