German Federal Institute for Risk Assessment

FAQ

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Biotin: Supplements can interfere with laboratory tests

This can complicate the diagnosis of conditions such as heart attacks and thyroid disorders

Biotin is a water-soluble B vitamin found in a wide variety of foods. It plays a role in fundamental metabolic processes involving protein, fat and carbohydrate metabolism.

Food supplements containing biotin are often advertised as having beneficial effects on the skin, hair and nails. Whilst the vitamin does contribute to maintaining the normal functions of the skin, mucous membranes and hair, the population in Germany already consumes sufficient amounts of biotin through their nutrition, meaning that additional intake via food supplements is not necessary.

Even in amounts far exceeding the dietary reference intake value, additional biotin intake is harmless to health, so the BfR has so far refrained from issuing a recommendation for maximum levels for biotin in food supplements and fortified foods. There is awareness that taking high-dose biotin supplements (150 micrograms (µg) or more per daily dose) can lead to false results in laboratory tests and thus to problems in medical diagnostics, e. g. of heart attacks, or in the interpretation of thyroid values.

The BfR therefore recommends that food supplements containing biotin carry a warning statement that individuals should inform their doctor or laboratory staff about their biotin intake prior to any necessary laboratory tests.

Below, the BfR has compiled the most important information on biotin in an FAQ.

What is biotin?

Biotin is a water-soluble B vitamin with wide prevalence in a variety of foods. In humans, it is an essential cofactor for enzymes and plays an important role in various metabolic processes.

In food, biotin is mainly bound to protein, but is also present in free form. In order for the body to take it up, the bound vitamin is released from its binding protein in the digestive tract and converted into free biotin.

The absorption rate from food is estimated at around 50 %. In contrast, biotin from medicines or food supplements, where it is predominantly present in its free form, is taken up at a rate of almost 100 %.

What is biotin needed for in the body?

Biotin performs important functions in the body as a coenzyme and is involved in a wide range of metabolic processes, including the synthesis of fatty acids and the breakdown of odd-chain fatty acids and certain amino acids. Biotin is also important for the regulation of gene expression, for cell growth and proliferation, and for the repair of DNA damage.

Which foods are good sources of biotin?

Biotin is found in numerous foods. Good sources include offal (particularly liver and kidney), porridge, certain vegetables such as soya beans or lentils, as well as mushrooms and eggs (especially egg yolk). Although milk and dairy products contain smaller amounts of biotin, they also make a significant contribution to biotin intake because consumption of these foods is generally high.

In addition, there are food supplements containing biotin and foods fortified with biotin in Germany, such as (multivitamin) mixed-fruit juices. According to the German National Nutrition Survey (NVS II), these foods, together with milk and dairy products, account for the largest proportion of biotin intake among adults in Germany.

What is the biotin intake of the population in Germany?

Data from the German National Nutrition Study (NVS II) show that the median dietary intake of biotin in women and men in Germany were around 36–42 micrograms (µg) and 43–48 µg per day, respectively. This means that the reference intake value of 40 µg per day, derived by the German Nutrition Society (DGE) for adults and adolescents aged 15 and over, is comfortably met or even exceeded by adults. Children and adolescents also generally achieve a biotin intake at or above the reference intake value through their usual diet.

What about risks of biotin deficiency, and when does it occur?

A nutrition-related biotin deficiency does virtually not occur in healthy people following a varied diet. It can only occur as a result of a very long period of an extremely unbalanced diet. In particular, a very high consumption of raw egg white over a long period is

problematic, because the glycoprotein avidin contained therein inhibits the intake of biotin in the intestine. Avidin loses this property when heated.

According to the German Society for Nutrition (DGE), high alcohol consumption, smoking and the use of certain medications (e. g. for the treatment of epilepsy) can also hinder the intake of biotin or accelerate its breakdown.

What about the health risks of biotin excess?

To date, no adverse effects have been observed from biotin intake far exceeding the reference intake value set by the German Society for Nutrition (DGE).

The former Scientific Committee on Food of the European Commission (Scientific Committee on Food; SCF) concluded in its risk assessment of biotin, based on the limited data available from observational studies, that with a biotin intake (from food and supplements) of up to approximately 100 µg per day, the risk of adverse health effects for the general population is low.

However, there is awareness that taking biotin supplements or medications (at doses of 150 µg or more per day) may lead to false results in laboratory tests and thus to problems in medical diagnostics (see also the question 'What should consumers bear in mind when taking biotin?'). The Federal Institute for Drugs and Medical Devices (BfArM) has also drawn attention to this:
https://www.bfarm.de/SharedDocs/Risikoinformationen/Pharmakovigilanz/DE/RHB/2019/rhb-biotin.html.

Is taking a biotin supplement advisable?

The body's requirement for biotin can generally be met through a varied diet. Additional biotin intake via food supplements is therefore not necessary for the healthy general population.

Are there regulated maximum levels for biotin in food?

Although the relevant regulations for food supplements and fortified foods in the European Union (Directive 2002/46/EC on food supplements and Fortification Regulation (EC) No 1925/2006) provide for the setting of maximum levels for the addition of vitamins and minerals to food supplements and fortified foods, no binding maximum levels have yet been established either national or European level. This also applies to biotin.

Important to know: Food supplements are available as tablets, coated tablets or powders. Even though they may look like medicines, they are not medicines. They are classified as foods intended to supplement the normal diet. As foods, they must above all be safe, meaning they must not cause any adverse effects. They must not be advertised for curing, alleviating or preventing diseases. Unlike medicines, which undergo an authorisation process, food supplements are subject only to a notification requirement with the German Federal Office of Consumer Protection and Food Safety (BVL). Manufacturers and distributors are responsible for the safety of the products. The monitoring of food

supplements available on the market and of manufacturing facilities is the responsibility of the food safety authorities in the German federal states.

What maximum levels does the BfR recommend for biotin?

The European Food Safety Authority (EFSA) has not derived a Tolerable Upper Intake Level (UL) for biotin, as no adverse health effects have been observed even at intakes well above the dietary reference intake (40 µg per day for adolescents and adults). In the BfR's view, therefore, based on the current state of knowledge, there is no need to set a maximum level for biotin in food supplements and fortified foods.

However, the BfR recommends that food supplements containing biotin should generally carry a warning statement that individuals who are due to undergo a laboratory test should inform their doctor or the laboratory staff of any current or recent intake of biotin. This is due to cases of biotin interfering with laboratory diagnostic tests that have gained awareness in recent years (see question: "What should consumers be aware of when taking biotin?").

What effects does taking biotin have on the skin, hair and nails?

Some biotin supplements are marketed for their beneficial effects on the skin, hair and nails.

The European Food Safety Authority (EFSA) has assessed the health claims submitted by manufacturers for biotin and concluded the following claims as scientifically substantiated: "Biotin contributes to the maintenance of normal hair" and "Biotin contributes to the maintenance of normal skin".

However, the fact that EFSA has approved these health claims regarding biotin, does not mean that taking biotin-containing food supplements necessarily has positive health effects on the skin or hair. In its assessment, the EFSA explicitly pointed out that the approval of these health claims does not imply that the population's intake of biotin is insufficient for the maintenance of normal hair. On the contrary, the population generally takes up sufficient amounts of biotin through their diet, so that no benefit to the skin or hair is to be expected from additional intake via food supplements.

Based on the study data provided, the EFSA was unable to confirm that consuming biotin in the diet helps to maintain healthy nails. Consequently, such claims are not permitted on food products.

What should consumers be aware of when taking biotin?

In recent years, there has been an increase in awareness of reported cases where clinical laboratory tests have yielded false results in connection with previous or current biotin supplementation.

This can be explained as follows:

Specific laboratory tests – known as immunoassays – utilise the interaction between biotin and the protein streptavidin for the detection of certain biomarkers (e. g. of hormones, cardiac, tumour or infection markers). One example is the measurement of the heart-

specific protein troponin, which is present in elevated concentrations in the blood when a person has suffered a heart attack. However, if biotin – particularly in high doses – is taken via medication or food supplements, the concentration of free biotin in the blood can increase so significantly that the biotin competes with the test reagents for the binding sites on the streptavidin and, depending on the test setup, more or less of the substance to be detected is measured – thereby distorting the test result. In the case of a heart attack diagnosis, this can, for example, mean that it cannot be clearly established whether a heart attack has occurred, or that a heart attack is detected too late. Biotin can also lead to falsely elevated levels of triiodothyronine (T3) and thyroxine (T4) or to falsely low levels of thyroid-stimulating hormone (TSH) in thyroid tests – and thus to the misinterpretation of hyperthyroidism (Graves' disease).

Such problems have been observed with various biotin dosages, but in most cases with oral biotin intake of 150 µg per day or more. To reduce the risk of laboratory tests being falsified by biotin – and thus of delayed or incorrect diagnoses – the BfR recommends that food supplements containing biotin carry a warning statement that individuals who need to undergo a laboratory test should inform their doctor or the laboratory staff about their biotin intake. For medicines containing biotin, a corresponding warning regarding potential interference with laboratory tests is mandatory in the package leaflet.

Who has an increased risk of false laboratory test results due to biotin?

People taking biotin supplements at doses of 150 µg or more per day – regardless of whether these are single-ingredient preparations, vitamin B complex preparations or other combination preparations containing biotin – are at increased risk of clinically significant false results in any necessary laboratory tests.

People with chronic kidney disease who have elevated biotin concentrations in their blood are also at increased risk.

Furthermore, the Federal Institute for Drugs and Medical Devices (BfArM) points out that particular caution is required with high-dose biotin therapy (in the milligram range). The same applies to newborns, children and pregnant women.

Further information on the BfR website

Biotin in food supplements can influence laboratory test results (only in German available)
https://www.bfr.bund.de/mitteilung/biotin-in-nahrungsergaenzungsmitteln-kann-labortestergebnisse-beeinflussen/

Recommended maximum levels
Proposed maximum levels for biotin in food, including food supplements (only in German available)

https://www.bfr.bund.de/veroeffentlichung/hoechstmengenvorschlaege-fuer-biotin-in-lebensmitteln-inklusive-nahrungsergaenzungsmitteln/

Further information on the microco website

Information page on biotin
https://www.microco.info/vitamins/biotin/

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the German Federal Ministry of Agriculture, Food and Regional Identity (BMLEH). It protects people's health preventively in the fields of public health and veterinary public health. The BfR provides advice to the Federal Government as well as the Federal States ('Laender') on questions related to food, feed, chemical and product safety. The BfR conducts its own research on topics closely related to its assessment tasks.

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