

## Communication 57/2023

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### **Omega-3 fatty acid supplements can increase the risk of atrial fibrillation in heart patients**

Medicines, but also food supplements such as fish oil capsules, can cause the undesirable effect

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Taking preparations containing omega-3 fatty acids can increase the risk of atrial fibrillation, a disorder of the heart rhythm, in people with existing or impending heart disease. This is the result of an evaluation of several clinical studies by the European Medicines Agency (EMA). In these studies, the patients took either omega-3 fatty acid-containing medicines or food supplements.

The clinical studies mainly examined patients who already had a cardiovascular disease (i. e. a disease affecting the heart or blood vessels) or who were at increased risk of developing one. The EMA's evaluation showed that the risk of atrial fibrillation depended on the dose of omega-3 fatty acids taken and was greatest at the highest tested dose of 4 grams per day.

Food supplements with omega-3 fatty acids are offered in the form of fish oil capsules, for example, and sometimes contain similar dosages as medicines. Unlike drugs, food supplements are freely available on the market and may also be taken over longer periods of time without medical supervision. Possible adverse health effects can therefore be more easily overlooked.

The German Federal Institute for Risk Assessment (BfR) recommends that particularly consumers with heart disease or corresponding risk factors should only take preparations containing omega-3 fatty acids, such as food supplements, in consultation with a doctor, especially over a longer period of time.

Moreover, it is important to consider that Omega-3 fatty acids are also found in fish. Regular fish consumption (once or twice a week) has health-promoting effects, e. g. on fat metabolism, but does not result in intake levels of omega-3 fatty acids that are associated with the health risks described above.

Food supplements are not intended to cure or alleviate a disease. Food supplements are not medicines, but foods that can supplement a normal diet. They must be safe and must not have any undesirable health effects.

Long-chain omega-3 fatty acids from fish oil such as DHA and EPA (docosahexaenoic acid and eicosapentaenoic acid) are deemed to have health-promoting properties, such as, among others, the prevention of cardiovascular and vascular diseases. Fish oil is therefore not only offered in food supplements, but is also used to fortify foods.

In this context, the BfR already assessed the health risk of an increased intake of the omega-3 fatty acids DHA and EPA in 2009 and pointed out that there was evidence of increased cholesterol levels, impairment of the immune defence in older people, increased mortality in people with heart disease and an increased tendency to bleed at high intake levels. The long-term effects of increased intake have also not been sufficiently investigated. The BfR therefore recommended setting maximum levels for the addition of DHA and EPA to food products. This recommendation is still valid.

The BfR does not consider it necessary for healthy people to take fish oil concentrates via food supplements, especially if they regularly consume fish.

As a consequence of the current scientific findings that the risk of atrial fibrillation increases in people with existing or impending heart disease, pharmaceutical companies (the marketing authorisation holders of medicines containing omega-3 fatty acids) have published a so-called Red Hand Letter in coordination with the Federal Institute for Drugs and Medical Devices (BfArM), in which they provide information about the risk of atrial fibrillation when using medicines containing omega-3 fatty acids.

[Red Hand Letter on medicines containing omega-3 fatty acids \(in german\)](#)

**Further information on Omega-3-fatty-acid**

Opinion: BfR recommends the setting of maximum levels for the fortification of foods with omega-3 fatty acids

[https://www.bfr.bund.de/cm/349/bfr\\_recommends\\_the\\_setting\\_of\\_maximum\\_levels\\_for\\_the\\_fortification\\_of\\_foods\\_with\\_omega\\_3\\_fatty\\_acids.pdf](https://www.bfr.bund.de/cm/349/bfr_recommends_the_setting_of_maximum_levels_for_the_fortification_of_foods_with_omega_3_fatty_acids.pdf)

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