German Federal Institute for Risk Assessment

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Ashwagandha: food supplements with potential health risks

Especially children, pregnant women, breastfeeding mothers and people with liver disease should avoid them

Food supplements containing preparations of ashwagandha (*Whitania somnifera*), also known as Indian ginseng or winter cherry, are available in regular shops and online shops as powders, capsules, liquids or teas. They are being advertised by food business operators by making reference to purported health benefits related to, for example, an increase in performance, improvement of sleep or coping with stress. However, the claimed positive effects have not been scientifically proven and the health risks of taking these herbal preparations have not yet been well investigated. Based on the available evidence, the German Federal Institute for Risk Assessment (BfR) recommends that especially children, pregnant and breastfeeding women and people with acute or pre-existing liver disease should not take supplements containing ashwagandha. Due to a lack of data and gaps in knowledge, the BfR also advises other population groups to exercise caution when using such products.

The available human studies primarily investigated potential benefits of ashwagandha preparations, while possible adverse effects were not systematically recorded. Reported acute effects of using supplements containing ashwagandha include digestive complaints such as nausea, vomiting and diarrhoea as well as drowsiness, headaches, dizziness, and skin rashes. There is also evidence that supplements containing ashwagandha may affect the immune system and the endocrine system (effects on cortisol and blood glucose levels and on thyroid and sex hormones). From a risk assessment perspective, case reports of liver damage associated with the consumption of supplements containing ashwagandha give rise to particular caution. However, the data currently available are not sufficient to allow a conclusive risk assessment and to draw more precise conclusions about the health risks. It has also not yet been possible to derive a health-based guidance value for a safe intake level on the basis of the available data.

Ashwangandha (Lat.: *Whitania somnifera*) is traditionally used in Ayurvedic medicine. It is mainly the root of the plant or preparations thereof that are used. Recently, herbal parts and preparations derived from the root, but also from leaves of ashwagandha, have been used in food supplements or teas in Europe. Among the wide range of phytochemical components, the so-called withanolides and alkaloids are considered the major biologically active constituents. However, based on the available data, it is not possible to clearly identify the substance(s) and dosages that may be responsible for the effects reported in the studies.

Studies to date suggest that the type and concentrations of the constituents in ashwagandha-based food supplements vary widely. This is partly due to the fact that mainly the root, but sometimes also other parts of the plant (i. e. the leaves) are used for supplements, and that different extraction methods are used to obtain the phytochemicals. Both the herbal parts used and the extraction method can affect the concentration of the biologically active constituents - and thus presumably also the biological effect of the supplement.

Possible adverse effects of ashwagandha or *Withania somnifera* have hardly been investigated in human studies to date. Studies carried out to investigate benefits on health, differed in the type of products administered, their dosages and formulations, but also in the study groups and the duration of intake. Furthermore, these studies did not systematically record possible adverse effects. Conclusions about a causal relationship between ashwagandha and the observed effects are also made considerably more difficult by the fact that ashwagandha supplements are often marketed as combination preparations.

The BfR already published a risk assessment on preparations and extracts from the root of *Withania somnifera* in 2012, based on the data available at that time. Back then, health concerns were raised about the use of such preparations, mainly due to evidence of interference with thyroid function and the fact that ashwagandha has historically been used as an abortifacient.

In the years 2020 to 2024, several European scientific institutions such as the *Technical University of Denmark (DTU)* in Denmark or "sister authorities" of the BfR (in the Netherlands (RIVM) and France (ANSES)), as well as the Australian *Therapeutic Goods Administration (TGA*) have compiled data from recent research on ashwagandha for renewed risk assessment. The results confirm and complement the BfR's previous risk assessment by indicating that supplements containing ashwagandha may affect blood glucose levels, sex hormones, and the central nervous system as well as the thyroid, adrenal glands and liver function. However, the data quality was still considered insufficient for a conclusive risk assessment and the derivation of safe intake levels - partly also because possible consequences of long-term intake have been insufficiently investigated to date.

Since 2017, however, several case reports have been published worldwide, including reports from Europe and also Germany, as well as suspected cases of (sometimes serious) adverse effects that may be associated with the use of supplements containing ashwagandha. Reported acute effects, some of which have also been reported in clinical studies, include digestive tract complaints such as nausea, vomiting and diarrhoea, as well as drowsiness,

headache, dizziness, and skin rashes. In particular, the reports regarding liver damage, including cases of acute liver failure, give reason for caution.

Overall, the available data suggest that there are individuals or groups of the population who may be particularly sensitive to ashwagandha. These also appear to include people with acute or pre-existing liver disease. Moreover, there is evidence that ashwagandha containing supplements can interact with other medications, for example with certain drugs that regulate blood glucose levels (antidiabetics), blood pressure (antihypertensives) or the immune system (immunosuppressants). For this reason, medical advice should be sought when taking certain medicines.

Based on the risk assessments published to date and the internationally registered case reports, the BfR and other European authorities advise against consuming food supplements containing ashwagandha. As there is a lack of data on the safety of ashwagandha for pregnant women, breastfeeding mothers and children, these population groups in particular are advised against using such preparations.

Important to know: herbal preparations ("botanicals") such as those based on ashwagandha belong to the so-called 'other substances' with a nutritional or physiological effect. Such substances are often added to food supplements, although their use has so far not been sufficiently regulated in the European Union. According to REGULATION (EC) No 1925/2006 of 20 December 2006, the following principle applies: If the possibility of harmful effects on health has been identified but scientific uncertainty persists, the substance shall be placed in Annex III, Part C (Substances under Community scrutiny) of the said Regulation. The BfR had already recommended (in German only) in 2012 to proceed accordingly with the root of *Withania somnifera*.

Food supplements containing herbal preparations should not be confused with medicinal products. Medicinal products undergo an official authorisation procedure before they are placed on the market. Food supplements, on the other hand, are legally regarded as foods intended to supplement the general diet of healthy people. There is no pre-market approval of food supplements in the sense of an official authorisation where the products are specifically assessed for their safety or suitability for the general population. The main responsibility for the safety of food supplements lies with the food business operators, i.e. the manufacturers, importers, suppliers or distributors. In Germany, the monitoring of food supplements on the market is the responsibility of the food monitoring authorities of the federal states. They randomly check whether the products offered on the market fulfil the legal requirements.

Further information on food supplements

FAQ on food supplements
https://www.bfr.bund.de/en/frequently_asked_questions_on_food_supplements-70347.html

Information and vitamins, minerals and other substances also offered as food supplements
https://www.microco.info/en/vitamine-homepage.html

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. The BfR advises the Federal Government and the States ('Laender') on questions of food, chemicals and product safety. The BfR conducts independent research on topics that are closely linked to its assessment tasks.

About mikroco.info

The internet portal www.mikroco.info provides information on vitamins, minerals and numerous other substances that we ingest with food or that are offered as food supplements. In addition, the individual pages contain the maximum levels of vitamins and minerals in food supplements and in fortified foods as recommended by the German Federal Institute for Risk Assessment (BfR).

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