

# HERBAL FOOD SUPPLEMENTS

Leaflet for consumers

Understanding herbal food supplements



Committee of Experts on  
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**French edition:** *Compléments alimentaires à base de plantes. Brochure à destination du grand public. Comprendre les compléments alimentaires à base de plantes.*

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# How are herbal food supplements regulated in Europe?

In the European Union (EU), herbal food supplements are regulated as foods and come under the General Food Law Regulation; as with all food supplements, they are not meant to treat or prevent any disease and should not be confused with or used as medicines.

Herbal food supplements should comply with current regulations governing:

- their composition (e.g. they should only contain ingredients that are authorised in food supplements, such as vitamins and plants/herbal extracts);
- how they are labelled (e.g. the label should state that they are food supplements and should provide information about the recommended quantity per daily intake, etc.);
- how they are advertised: health claims on the label should not be misleading and the packaging should not suggest that a particular food supplement will provide an adequate source of all essential nutrients.



The responsibility for the safety of products and compliance with food law lies with food business operators who are legally responsible for ensuring that their products meet the food law requirements of your country. The EU has a specific legal framework regulating these products, and

some countries have also implemented a notification procedure under which the food business operator is requested to inform the competent authority when they launch a new food supplement on the market and to provide a copy of the product label. However, this is a “for information-only” notification and does not mean that the food supplement itself, its composition or its label have been assessed by the competent authority.



As for any other food, food supplements are controlled by national competent authorities based on risk assessment criteria. The authorities are responsible for analysing the product composition, verifying the labelling, and inspecting manufacturers. Any food supplements that do not meet all applicable requirements are taken off the market by the authorities to protect consumers.

## **Who monitors food supplements (including herbal food supplements)?**

Under EU legislation, it is the responsibility of food business operators to ensure that any food (including food supplements) they place on the market is safe and that it complies with legal requirements. National competent authorities are also required to have systems in place to monitor food that is already on the market and to ensure that food business operators meet their obligations. Food supplements can be controlled at various levels (e.g. during their manu-

facture, when they are imported, when they are launched on the market) by selective and/or random checks performed by national competent authorities (based, for instance, on the history of the operators or previous known non-conformities), who can prevent the food supplement from being placed on the market or withdraw or recall it if it is considered unsafe for consumers or does not comply with regulations.

## Can herbal food supplements be used as medicines?

Herbal food supplements are foods, not medicines. They should never be used instead of a medical treatment.

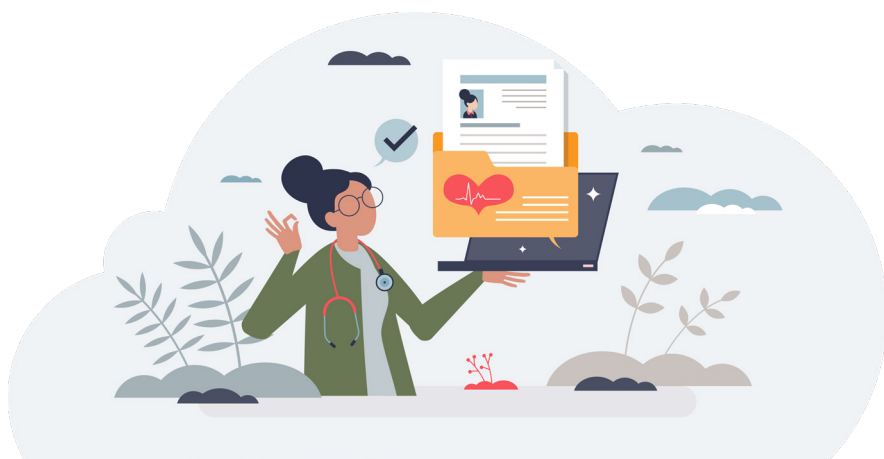
A medicine is a substance or combination of substances that is used to diagnose, prevent or treat a disease. Before a medicine can be launched on the market, it must go through an official authorisation procedure (or, in the EU, approval by the EU competent bodies), during which its quality, efficacy and safety are assessed by national competent authorities. The safety of medicines is regularly monitored and evaluated for as long as the medicine is on the market, by both the marketing authorisation holder (who is legally responsible for the product) and the competent authorities.



On the other hand, herbal food supplements (and food supplements in general) are

foods that are intended to supplement the consumer's normal diet to improve overall wellness. Therefore, unlike medicinal products, they cannot be used to diagnose, prevent or treat a disease.

While food supplements do not have to undergo an authorisation procedure prior to their launch on the market, they must nonetheless be safe to use and this safety is the responsibility of food business operators. Their safety is also monitored (usually by performing selective and/or random checks) by the national competent authorities whose role is to check that food supplements on the market comply with the relevant legislation. A herbal food supplement's label should always state "food supplement".



## What can herbal food supplements be used for?

Herbal food supplements are concentrated sources of nutrients and other substances. They have a nutritional or physiological effect and are used to supplement the diet. They do not replace a normal, varied diet and, unlike medicines, are not intended to prevent or treat a disease. Consequently, they should never be taken instead of a medical treatment.

Food supplements should only be used by people whose physiological parameters are within the normal range, but who wish to optimise them.

## Are there any risks associated with taking herbal food supplements?

Most food supplements (including herbal supplements) are safe; however, some of them can have effects on the body, so always be alert to the possibility of an adverse reaction.

These problems can occur especially if you:

- do not comply with the instructions for use given on the product label (dose) and take too much of a food supplement which might cause anything from mild to severe adverse reactions (e.g. high doses of *Valeriana*)



*officinalis* may result in excessive dizziness and sleepiness);

- combine supplements that should not be taken together, because they can interact with each other and have a negative impact on health (e.g. *Ginkgo biloba* combined with *Allium sativum* (garlic) may increase the risk of bleeding);
- use supplements together with medications (prescription or over-the-counter) as this may lead to drug-food supplement interactions that might cause problems (e.g. *Hypericum perforatum* L. (St. John's wort) can accelerate the breakdown of many medicines including some antidepressants and oral contraceptives and thus reduce their effectiveness);
- take supplements instead of a medical treatment: supplements are not intended to treat, mitigate, prevent or cure diseases and this may lead to significant delays in seeking medical attention for your condition.

Lastly, there may also be additional risks due to the possible presence of undeclared medicinal product ingredients, poor product quality, possible confusion between very similar plants (e.g. some species of ginseng are dangerous), lack of knowledge of possible effects of many plants (especially those of non-European origin) and potential contamination (e.g. with micro-organisms, fungal and plant toxins, pesticides and heavy metals),



in particular when products are bought from non-reputable food business operators and suppliers or unsure sources (e.g. unregulated and/or illegal online sales platforms).

## Can herbal food supplements interact with medicines?

Yes, interactions between herbal food supplements and medicines are possible and can have serious clinical consequences.

If you are using prescription or over-the-counter medicines, read the instructions on the label very carefully, checking for possible interactions, and always consult your healthcare professional before taking herbal food supplements. Some supplements can decrease the effects of medicines, while others can increase both their effects and their unwanted side effects. For instance, *Hypericum perforatum* L. (St. John's wort), which is often taken to relieve depression, can interact with oral contraceptives, reducing their efficacy. Another example is ginseng (*Panax ginseng*) (often used as a tonic to boost energy and vitality) which may reduce the blood levels and anti-coagulant effects of blood thinners like warfarin. On the other hand, garlic (*Allium sativum*), which is believed to have a positive effect on the heart and blood vessels, may also interact with warfarin but intensifies its effects, making the risk of bleeding higher.



It is important that you read the label of the supplement and any other information provided with it carefully, to make sure that it is suitable for you and that you use it as described on the label.

## What should I do before buying/ taking herbal food supplements?

Under normal circumstances, a varied, balanced diet provides all the nutrients necessary for healthy development and function, so in most cases food supplements may not be necessary. However, there can be exceptions to this general rule and some people may feel the need to boost their nutrient intake with food supplements, including herbal food supplements.



While they can be beneficial for health, food supplements are foods: unlike medicines, they are not supposed to prevent or treat diseases or have therapeutic properties and should not claim to do so either in their advertising or on their packaging. However, EU law permits claims that a supplement supports growth, development and the normal functions of the body and reduces the risk of disease, provided that they have been scientifically assessed and confirmed by the European Food Safety Authority (EFSA) and authorised by the European Commission (*note*: only a limited number of health claims are currently authorised at EU level). Most claims for herbal food supplements are still awaiting completion of the authorisation process (“on-

hold claims”) and may be used under the responsibility of the food business operator provided they comply with national regulations. If nutrition or health claims are made for a product that you are thinking of using, you may wish to check the list of authorised claims (available on the [European Commission website](#)) or discuss the claims with your healthcare professional.

If you are ill, you should never use herbal food supplements instead of your medication and should always seek medical advice.

It is recommended to discuss your intention to use a herbal food supplement with a healthcare professional, especially if you belong to a population that is considered more at risk (e.g. pregnant and breast-feeding women, the elderly), suffer from one of more diseases, are using other food supplements and/or medication, or are scheduled to undergo a surgical or other procedure.

## **Where can I buy herbal food supplements?**

Herbal food supplements can be purchased without a prescription from a variety of places, including pharmacies, non-pharmacy outlets, any shop authorised to sell food (e.g. health food stores and supermarkets) and from the internet.

Some of the herbal food supplements on the market are of questionable value and may even be illegal. Their quality and price

may vary greatly, influencing your choice. Therefore, it is recommended to buy herbal food supplements from reputable retail outlets (that operate in line with EU requirements and /or national food safety legislation).

If you are planning to buy a herbal food supplement, you may wish to discuss your intention with your healthcare professional beforehand and look for information from trustworthy and official sources (see list of websites below). You are advised to buy herbal food supplements via trustworthy channels and from reputable suppliers (particularly if you are purchasing these products online) (please also see [Can I buy herbal food supplements online?](#)).



Always choose a brand/manufacturee that you can trust. Although it may take time, it is advisable to check the label of the supplement to find out who the brand/manufacturee is, their contact information and the composition of the herbal product. You can also visit the brand/manufacturee's website or even call their customer service line to find out what tests are carried out to prove that the supplement is safe, what quality measures are in place and how it is manufactured.

You should also make sure that the product you intend to buy complies with the regulations in force (see [How are herbal food supplements regulated in Europe?](#)) and check the label for other information such as the recommended daily dose, composition, instructions for use and any special

warnings (e.g. a warning statements for specific groups of people such as pregnant or breastfeeding women).

Lastly, you should pay attention to anything that appears “suspect”, such as a lack of detail about the product composition, reference to therapeutic indications, excessive promises (e.g. significant weight loss in 2 weeks or “miracle cures”), a particularly low price or “too good to be true” discounts. In such cases, do not buy the product.

## Can I buy herbal food supplements online?

You can buy herbal food supplements from the internet, but you should always bear in mind that there may be certain risks associated with using supplements obtained from an unreliable source (which may include the internet).

European and national legal provisions for herbal food supplements apply, irrespective of the distribution channel. However, it should not be assumed that products purchased as herbal food supplements directly from manufacturers/distributors located outside Europe comply with European and national food regulations.

The risks include poor quality products (e.g. containing heavy metals, germs, mycotoxins, pesticides), possible confusion between very similar plants, presence of undeclared active pharmaceutical ingredi-



ents or of illicit and dangerous substances deliberately introduced into a product without the consumer's knowledge, unauthorised health claims, inadequate instructions for use and poor storage or shipping conditions.

Therefore, if you decide to buy a food supplement online, make sure that the web site corresponds to a well-identified company, with a physical address that you can contact if necessary, and with a customer service line. You should also check that all the mandatory information is available (e.g. name of the product, list of ingredients, quantity of active ingredients, precautions for use, daily dose) and the labelling is in the language of the country you are buying the product from.

## **How should I take my herbal food supplement and what is the proper dose?**

It is important to know how, when and for how long you should take herbal food supplements.

To this end, you should read carefully both the product label and (when available) the consumer information leaflet, and follow the instructions given.

Make sure that you do not:

- exceed the recommended dose;
- take herbal food supplements other than described on the label or use them on a prolonged or repeated basis

or in combination with other food supplements;

- take herbal food supplements in combination with medicines (whether prescription or over-the-counter) without first asking your healthcare professional. You should also talk to your healthcare professional if you are already taking other food supplements;
- use herbal food supplements instead of medicines;
- store herbal food supplements inappropriately and not as described on the label.

If you do not know how to take a given herbal food supplement or you have any questions/doubts, you should ask your healthcare professional for advice. This is even more important if you are in a population for which specific precautions are



required, for example, if you are pregnant, breastfeeding or elderly, if you have certain health conditions, are using other food supplements and/or medications, or are scheduled to undergo surgery.

## What should I do if I experience an adverse event when using a herbal food supplement?



If you think that you have experienced an adverse reaction after taking a herbal food supplement, you should:

1. STOP taking the supplement immediately;
2. SEEK medical advice and/or care;
3. REPORT the adverse reaction to your healthcare professional and/or, if applicable, to the competent authority;
4. REPORT the adverse reaction to the food business operator.

## How can I find out more about herbal food supplements?

Read labels carefully and talk to your healthcare professional before buying or taking any herbal food supplement (especially if you are under medical treatment or belong to a population that is considered more at risk, e.g. pregnant and breastfeeding women, the elderly).

Check information for instance in the following trustworthy websites:

<https://www.efsa.europa.eu/en/topics/topic/food-supplements>

[https://medlineplus.gov/druginfo/herb\\_All.html](https://medlineplus.gov/druginfo/herb_All.html)

Website of your national competent authority (non-exhaustive list available here: ([https://food.ec.europa.eu/index\\_en](https://food.ec.europa.eu/index_en)))

You can also search for medical and scientific studies on specific herbal supplement ingredients using PubMed (i.e. one of the most widely accessible resources that provides access to over 35 million journal citations for biomedical literature from MEDLINE, life science journals, and online books).



## List of authors

This leaflet was produced under the overall co-ordination of the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC), whose Secretariat is provided by the European Directorate for the Quality of Medicines & HealthCare (EDQM) (Council of Europe).

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The growing availability and use of herbal food supplements have raised concerns about their safe and appropriate use, quality, potential interactions with medication and/or other food supplements, and misleading claims.

The aim of this leaflet is to provide consumers with easy-to-understand, accessible and user-friendly information to help them make informed decisions about the use of herbal food supplements and ensure that these products are taken safely and properly. It highlights safety considerations, regulatory aspects and the importance of consulting a healthcare professional before buying or using these products, particularly if the consumer belongs to a special population, such as pregnant or breastfeeding women and older people. It also emphasises the need to follow labelling instructions or healthcare professionals' recommendations and to purchase herbal food supplements from reliable sources.



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