



## **Position of the French Human Milk Bank Association (FHMBBA) on breastfeeding teas and other lactation stimulants, particularly fennel-based teas**

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The French National Agency for the Safety of Medicines and Health Products (ANSM) and, more recently, the European Medicines Agency (EMA) have warned of the potential danger of consuming medicinal products containing aniseed-based substances such as fennel. Of particular concern are products known as galactogens or lactation stimulants, in which fennel may be present in varying quantities, possibly in combination with aniseed. The safety profile of fenugreek, another plant used as a galactogen, is also still under discussion.

Yet these products are consumed quite frequently by breastfeeding women, in the form of herbal teas or dietary supplements (capsules, sachets).

The question of their value in the context of lactation perceived - often wrongly - as insufficient by the mother, is therefore worth asking today.

### **Proven toxicity in animals and possible toxicity in humans**

In its assessment report of 31/01/24, the EMA reported the carcinogenic, genotoxic and hepatotoxic effects of estragole, a molecule present in the fruits of fennel and aniseed. At present, these effects have only been demonstrated in rodents, but they could be expressed in a similar way, using the same mechanisms, in humans. In addition, this toxicity has only been found when estragole is taken in high doses, and the EMA considers that it is unlikely that this molecule will have a carcinogenic effect in the context of normal food consumption. ***However, as the quantity of estragole is generally not clearly indicated on products containing it, the EMA recommends that, as a precaution, it should be used for as short a time and at as low a dose as possible (less than 14 days, preferably taken once, at a maximum daily dose of 0.05 mg for adults).***

The ANSES (French National Agency for Food, Environmental and Occupational Health and Safety) has also received reports of adverse effects linked to the consumption of fenugreek. Digestive disorders (liver toxicity, diarrhoea, vomiting, etc.), allergic disorders (local and respiratory disorders such as allergic rhinitis or asthma), metabolic disorders (hypoglycaemia observed at high doses) and dizziness were reported. As a result, the use of fenugreek is not currently recommended in either Europe or North America.

### **Unproven efficacy of galactogenic plants**

Fennel and aniseed, like fenugreek, have been used for centuries as lactation stimulants. However, as a number of institutions and authorities have pointed out,



notably the Academy of breastfeeding medicine (ABM) and ANSES, there is little or no scientific proof of the efficacy of these plants and lactogenic products. The studies, which are few in number, of poor quality and contradictory, do not lead to any convincing conclusions. Their mechanism of action, and indeed their passage through milk, are still unknown to this day.

### **Validated strategies to be proposed as a priority in cases of lactation insufficiency**

In the case of proven and objective insufficient lactation, the only validated solution is to optimise breastfeeding by providing the breastfeeding mother with professional guidance and support. He or she may recommend increasing milk production through frequent and regular drainage and stimulation to meet the principle of supply and demand, skin-to-skin contact, closer observation of the signs that the newborn or infant is ready to feed, adjustment or correction of the position and latch of the breast, and optimisation of feedings.

**In conclusion, considering studies suggesting the potential toxicity of substances and products that have not been shown to be effective in stimulating lactation, the French Human milk Bank Association (ADLF) recommends the utmost caution in the use of fennel-based products, preferring to use the only strategies recognised as effective in stimulating lactation.**

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