

Reviews by other risk assessment bodies

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15. Ginger is included in the official pharmacopoeias of several western countries. Ginger is classified as 'Generally Recognised as Safe' (GRAS) by the United States Food and Drug Administration (FDA). However, few specific studies have been carried out to evaluate the safety of ginger use during pregnancy and lactation. A report by the National Institute for Health and Care Excellence (NICE) cites a number of short duration trials which have been conducted in pregnant women (NICE, 2021).

16. In 2008, the Danish company Ferrosan A/S withdrew their product GraviFrisk – a product containing 6 g of dried ground ginger – from market, due to concerns around the lack of safety data with respect to the use of supplements containing highly concentrated ginger extracts by pregnant women (Dietz *et al.*, 2016).

17. In their 2012 report on ginger root in powdered form, the European Medicines Agency (EMA) concluded “The ginger extract dosages to provoke acute toxicity are high and much higher than usually administered dosages (factor of 10-15 for an adult). There is some evidence that ginger root may cause rodent testicular weight to increase by repeated high dosages of ginger root extract (2,000 mg/kg). Ginger root has mutagenic as well as antimutagenic properties in microbial test systems. Developmental toxicity studies in rats are difficult to interpret, however, it is probably not a cause for concern. In general, toxicity studies of ginger are considered inadequate at least regarding genotoxicity, carcinogenicity and, partially, reproductive and developmental toxicity.”

18. The Norwegian Food Safety Authority issued a warning regarding the use of ginger supplements and ginger-containing shots during pregnancy. This was based on a risk assessment carried out by the Danish Technical University and the Danish Veterinary and Food Administration (DTU, 2018). The assessment, based on animal studies, including one in which rats were treated with a freshly grated ginger preparation with ginger at concentrations of 20-50 g/L in water, found that even the lowest dose, 20 g/L – the equivalent of 1,784 mg/kg bw, increased the incidence of abortion in rats. The Norwegian Food Safety Authority concluded that while women would consume less ginger (124-329 mg, which is equivalent to 1.8-4.7 mg/kg bw, assuming a body weight of 70 kg), there remains cause for concern and fetal risk cannot be excluded.

19. Recently, the Finnish Food Authority issued a recommendation against the use of products containing ginger concentrate or extract, ginger tea and food supplements containing ginger by pregnant and breastfeeding women, infants and toddlers, schoolchildren, the elderly and individuals with weakened immunity (Finnish Food Authority, 2019). It was noted that the concentrates contained substances that may be harmful and safe consumption levels were unknown.

20. The Expert Panel for Cosmetic Ingredient Safety (U.S.) assessed the safety of ginger-derived ingredients for use in cosmetics and determined that they are safe in cosmetics in the present practices of use when formulated to be non-sensitising (Belsito, 2021). The report describes a number of human and animal studies where ginger was administered orally, including a short-term clinical study where seventy participants were given an oral dose of either steamed ginger extract (200 mg in capsule form; n = 36), or a placebo (n = 34), daily. All clinical test results were normal, and all participants completed the study. No extract-related adverse effects were observed.