Existing authorisations and Mechanism of action - Raspberry leaf tea

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Existing authorisations

11. In their review on the safety of raspberry leaf, the EMA's Committee on Herbal Medicinal Products (HMPC) highlighted that while clinical studies had not found a higher incidence of adverse pregnancy outcomes associated with raspberry leaf use, treatment durations had generally been short and only a small number of pregnant women were included in the trials (EMA, 2014). It was also highlighted that there were insufficient data on genotoxicity, carcinogenicity, reproductive and developmental toxicity to assess safety.

12. The HPMC recognised the traditional medicinal uses of raspberry leaf for the symptomatic relief of dysmenorrhea, as an astringent gargle, and for the symptomatic treatment of mild diarrhoea, and considered that these could be recognised as safe based on a history of traditional use. However, the HPMC concluded that the evidence regarding the efficacy and safety of raspberry leaf during pregnancy and lactation was lacking and that raspberry leaf could not be recommended for pregnant or lactating women, or in children and adolescents under 18 years of age (EMA, 2014).

Mechanism of action

In vitro and animal studies

13. The mechanism by which raspberry leaf may exert its alleged therapeutic effects during pregnancy is poorly understood (Bowman *et al*., 2021). Hastings-Tolsma *et al*. (2022) hypothesised that raspberry leaf's role in promoting parturition may be related to: its inflammatory, vasodilatory and antioxidant effects; its ability to promote apoptosis in cervical and myometrial cells; and the effects of the isoflavone genistein. However, limited and at times contradictory evidence was given to support these claims.

14. Six studies were identified, which had investigated the effects of raspberry leaf extract(s) on uterine and other types of smooth muscle *in vitro* and/or in animals (Burn and Withell, 1941; Beckett *et al*., 1954; Bamford *et al*., 1970; Rojas-Vera, Patel and Dacke, 2002; Zheng *et al*., 2010; Olson and DeGolier, 2016). However, results from these studies were highly variable, with some reporting a stimulatory effect and others reporting a relaxant effect. These differences have been attributed to differences in the composition of raspberry leaf preparations, dosages, extraction methods, animal tissue, the pregnancy status of the uterus/uterine tissue, baseline muscle tone, and whether or not the raspberry leaf was tested *in vitro* or *in vivo* (Bowman *et al*., 2021).

Human studies

15. A case series, by Whitehouse (1941), reported the effects of 1.30-2.59 g crude raspberry leaf extract or 20 oz. 5% raspberry leaf tea, administered via a uterine bag, on the uterine muscle of three post-partum women. Based on the findings, it was concluded that: "the main effect [of raspberry leaf was] relaxation of the uterine muscle."