



## Anise

Revised: May 1, 2019.

## Drug Levels and Effects

### Summary of Use during Lactation

Anise (*Pimpinella anisum*) seeds contain anethole, which is a phytoestrogen. Anise is a purported galactagogue, [1][2][3][4][5][6] and is included in some proprietary mixtures promoted to increase milk supply; however, no scientifically valid clinical trials support this use. Galactagogues should never replace evaluation and counseling on modifiable factors that affect milk production.[7] Maternal anise ingestion reportedly imparts an odor to breastmilk,[8] possibly because anethole is excreted into breastmilk.[9] Anise is "generally recognized as safe" (GRAS) as a flavoring by the U.S. Food and Drug Administration. Elevated liver enzymes occurred in a woman taking Mother's Milk Tea, which contains anise.[10] Excessive maternal use of an herbal tea containing anise and other herbs appeared to cause toxicity in two breastfed newborns, consistent with toxicity caused by anethole.

Dietary supplements do not require extensive pre-marketing approval from the U.S. Food and Drug Administration. Manufacturers are responsible to ensure the safety, but do not need to *prove* the safety and effectiveness of dietary supplements before they are marketed. Dietary supplements may contain multiple ingredients, and differences are often found between labeled and actual ingredients or their amounts. A manufacturer may contract with an independent organization to verify the quality of a product or its ingredients, but that does *not* certify the safety or effectiveness of a product. Because of the above issues, clinical testing results on one product may not be applicable to other products. More detailed information [about dietary supplements](#) is available elsewhere on the LactMed Web site.

### Drug Levels

*Maternal Levels.* Eighteen lactating women were given 100 mg of trans-anethol in a capsule on 3 test days. Milk samples were collected every 2 hours for 8 hours starting at the time of ingestion. Trans-anethol was detected in milk at all collection times, with the average concentrations of 2 mcg/L at 0 hours, 9.9 mcg/L at 2 hours, 9.2 mcg/L at 4 hours, 7.3 mcg/L at 6 hours and 4.3 mcg/L at 8 hours after the dose. The average peak anethol concentration in milk was 23.2 mcg/L. Only small amounts of anethol glucuronide metabolites were present in the milk samples.[9]

Five women who were nursing infants between 6 and 55 weeks of age drank 950 mL of fennel-anise-caraway tea (Messmer Ostfriesische Tee Gesellschaft Laurens Spethmann GmbH & Co. KG, Sevetal, Germany). The main odorant components of the tea are the following terpenes: limonene, 1,8-cineole, fenchone, estragole, carvone,

trans-anethole, p-anisaldehyde and anisketone. Mothers collected milk samples at 30 minutes, 1 and 2 hours after ingesting the tea. Ingestion of the tea did not increase the overall terpene content of the milk, but there was wide variation from mother to mother. Some mothers had high background levels of some terpenes, probably from other foods or person care products. In addition, a sensory panel found no significant change in the odor profile of the breastmilk samples compared to blank samples.[11]

*Infant Levels.* Relevant published information was not found as of the revision date.

## Effects in Breastfed Infants

Two breastfed infants, aged 15 and 20 days, were admitted to the hospital for a reported lack of weight gain in the previous 7 to 10 days, caused by "difficult feeding". The parents reported restlessness and vomiting during the past day. One of the mothers also reported feeling drowsy and weak. On examination, the infants were afebrile but had hypotonia, lethargy, emesis, weak cry, poor sucking and weak responses to painful stimuli. Infant laboratory values, electrocardiograms and blood pressures were normal, and septic work-ups were negative. Both mothers had both been drinking more than 2 liters daily of an herbal tea mixture reportedly containing licorice, fennel, anise, and goat's rue to stimulate lactation. After the mothers discontinued breastfeeding and the herbal tea, the infants improved within 24 to 36 hours. Symptoms of the affected mother also resolved rapidly after discontinuing the herbal tea. After 2 days, breastfeeding was reinstated with no further symptoms in the infants. Both infants were doing well at 6 months of age. The authors attributed the maternal and infant symptoms to anethole, which is found in both anise and fennel; however, the anethole levels were not measured in breastmilk, nor were the teas tested for their content.[12]

A small manufacturer-sponsored, double-blind, randomized study compared Mother's Milk tea (Traditional Medicinals, Sebastopol, CA) to lemon verbena tea in exclusively breastfeeding mothers with milk insufficiency. Each Mother's Milk tea bag contained 350 mg of anise fruit as well as several other herbs. Mothers were instructed to drink 3 to 5 cups of tea daily. No differences were seen between groups in infant digestive, respiratory, dermatological, and other maternal-reported adverse events. No differences were seen in the growth parameters of the breastfed infants between the two groups.[13]

## Effects on Lactation and Breastmilk

A group of 5 nursing mothers were given no herb for 5 days, 15 mL of a 5% infusion of anise 3 times daily for 10 days, followed by another 5-day control period from days 15 to 20. Their diet and environment were kept constant during the study period. Milk volume was measured daily and milk fat percentage was measured on days 5, 10, 15 and 20. The increase in milk volume was variable, from substantial increases to no effect to decreases in volume at the end of the study period. No overall changes in milk fat were observed.[14] Because of the lack of randomization, blinding and controls, and small number of participants, no valid conclusion can be made from this study on the galactagogue effects of anise.

In an uncontrolled, nonblinded study, 5 nursing mothers were given 4 cups of anise tea (preparation method not stated) daily to determine if milk production was improved. The measured endpoint was duration of lactation in the current pregnancy compared to the previous pregnancy based on maternal reporting. Treated women had trivial increases in duration of lactation from 10 days in the previous pregnancy to 15 days with use of the tea. [15] Because of the faulty study design and small number of participants, no valid conclusion can be made from this study on the galactagogue effects of anise.

One hundred fifty-eight mothers in Iran of who reported difficulty in breastfeeding were given either a proprietary mixture of herbs (Shirafza Drop) or a chlorophyll solution as a placebo. The herbal mixture contained the purported galactagogues fennel, anise, cumin, black seed, and parsley. Infant ages ranged between 0 and 6 months and they were exclusively breastfed. Weight gain of the infants was measured over time. No

difference in infant weight gain was seen between the two groups of infants.[16] Blinding and randomization in this study is unclear.

A randomized trial assigned mothers of preterm infants to receive either a purported herbal galactagogue tea twice daily, a fruit tea twice daily or nothing. The galactagogue tea mixture (Natal, Hipp [Turkey]) contained 1% stinging nettle as well as melissa, caraway, anise, fennel, goat's rue, and lemon grass in unspecified amounts. All mothers received similar breastfeeding advice from the same nurse and two groups were told that the tea would increase milk production, but compliance with the study teas was not assessed. Mother used breast pumps to extract and measure their milk and output on day 1 and day 7 of the study were compared. Although the increase in volume of extracted milk was greater in the galactagogue tea group, there was no difference in maternal serum prolactin between the groups at 7 days. No difference in infant weight gain was seen between groups, although the authors stated that additional supplementation was provided to all infants in addition to the pumped milk.[17] The study was not blinded, the randomization method was not stated, intent-to-treat analysis was not performed, and some of the numerical results were internally inconsistent, so the quality of the study was poor.

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## Substance Identification

### Substance Name

Anise

### Scientific Name

Pimpinella anisum

### Drug Class

Breast Feeding

Lactation

Complementary Therapies

Galactagogues

Phytotherapy

Plants, Medicinal