



## Goat's Rue

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CASRN: 84650-07-7

## Drug Levels and Effects

### Summary of Use during Lactation

Goat's rue (*Galega officinalis*) leaves and flowering tops contain numerous guanidine derivatives, including galegine which may cause hypoglycemia. Goat's rue is widely used internationally as a galactagogue.[1-4] No scientifically valid clinical trials support this use, although some old, poorly controlled studies found an effect. Galactagogues should never replace evaluation and counseling on modifiable factors that affect milk production. [5,6] Although it has a long history of use as a galactagogue, very limited scientific data exist on the safety and efficacy of goat's rue in nursing mothers or infants. In general, goat's rue is well tolerated, but it might cause hypoglycemia, so caution should be used in women taking antidiabetic drugs. Diarrhea and hepatomegaly occurred in a woman taking fennel, fenugreek, and goat's rue as galactagogues.[7]

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

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

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## 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, but not goat's rue; however, the anethole levels were not measured in breastmilk, nor were the teas tested for their content.[8]

## Effects on Lactation and Breastmilk

A group of 5 nursing mothers were given no herb for 5 days, 15 mL of a 5% of goat's rue infusion orally 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 goat's rue had no effect on milk volume or fat content.[9] 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 goat's rue.

Goat's rue extract (Galegran, Rieswerke, [Graz, Austria]) was given in an unspecified dose to increase the milk supply in an old, uncontrolled observational study of 336 women whose milk production was thought to be lower than normal. Increased milk output of 30 to 60% was observed.[10] Because of the lack of randomization, breastfeeding support, and placebo control no valid conclusion can be made from this study on the galactagogue effects of goat's rue.

In another old study that was not blinded, randomized or placebo controlled, goat's rue extract (Galegran, Rieswerke, [Graz, Austria]) was given in an unspecified dose to 50 postpartum women from the third to fifth days postpartum. Fifty untreated women were used as comparators. The milk output increased by 75% in the untreated women and by 125% in the treated women, but the volumes of milk were spread over wide ranges. Also, the quality of milk was determined based on the dry weight values of fat, protein and lactose in another 100 women (50 treated and 50 untreated). The increase in milk resulted in a proportional increase in the tested components; however, the differences were all in the normal range and not statistically significant.[11] Similar to the above study, no valid conclusion can be made from this study on the galactagogue effects of goat's rue.

Sixty-six postpartum mothers (22 in each of 3 groups) with no concurrent illnesses were randomly assigned to receive an herbal tea, placebo, or nothing after delivering healthy, fullterm infants. Mothers in the herbal tea group received at least 3 cups daily of 200 mL of Still Tea (Humana-Istanbul, Turkey; containing hibiscus 2.6 grams, fennel extract 200 mg, fennel oil 20 mg, rooibos 200 mg, verbena [vervain] 200 mg, raspberry leaves 200 mg, fenugreek 100 mg, goat's rue 100 mg, and, vitamin C 500 mg per 100 grams, per manufacturer's web site November 2011). A similar-looking apple tea was used as the placebo. All women were followed by the same nurse and pediatrician who were blinded to what treatment the mothers received. Mothers who received the Still Tea produced more breastmilk with an electric breast pump on the third day postpartum than mothers in the other groups. The infants in the Still Tea group had a lower maximum weight loss, and they regained their birth weights sooner than those in the placebo or no treatment arms. No long-term outcome data were collected. Because many of the ingredients in Still Tea are purported galactagogues, including goat's rue, no single

ingredient can be considered solely responsible for the tea's effects, although the authors attributed the action to fenugreek.[12]

An herbal tea containing goat's rue, fenugreek, hibiscus, fennel, rooibos, vervain, raspberry, and vitamin C (Humana Still-Tee, Humana GmbH, Herford, Germany) or water was randomly given to nursing mothers in a dosage of 3 cups daily beginning on the day of delivery. Several markers of antioxidant capacity were measured in breastmilk on day 1 and again after 7 to 10 days. No difference was found in the markers between mothers who received the tea and the water.[13]

In a randomized, double blinded study, a placebo or galactagogue containing 5 grams of a mixture of silymarin-phosphatidylserine and *Galega* (goat's rue) in a commercial product (Piulatte Plus, Milte) was given once daily to mothers of preterm infants. Phosphatidyl serine purportedly has improved bioavailability over silymarin alone. The placebo group received 5 grams of lactose once daily. The medication or placebo was given from day 3 to day 28 postpartum. Mothers pumped using a breast pump every 2 to 3 hours during the day and as desired at night. Milk production was measured on days 7, 14 and 28 postpartum. Daily milk production averaged 200 mL in the treated group and 115 mL in the control group. The total amount of milk produced during the study period and the proportion of women producing more than 200 mL daily was greater in the treated group than controls on days 7 and 28.[14] Mothers were contacted at 3 and 6 months postpartum concerning breastmilk production. Of the 89 mothers who responded satisfactorily at 3 months, more mothers who had received silymarin-galega were exclusively breastfeeding than those who received placebo (22/50 vs 12/50). Also, more mothers were feeding more than 50% breastmilk to their infants in the treatment group than the placebo group (29/50 vs 18/50). At 6 months postpartum, more mothers were feeding more than 50% breastmilk to their infants in the treatment group than the placebo group (22/50 vs 12/50). These differences were statistically significant.[15]

A survey was conducted on 238 mothers in Italy who were using a commercial goat's rue supplement that also contained vitamins and magnesium (Lactogal Plus, Loacker-Remedia, Italy) as a galactagogue. Sixty-seven percent of mothers felt there was an increase in milk production and 88% felt that the product had benefitted the breastfeeding experience. Ninety-nine percent of mothers rated the tolerability as good or very good.[16] No actual measurements of breastmilk production were performed.

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

Goat's Rue

### Scientific Name

*Galega officinalis*

### CAS Registry Number

84650-07-7

### Drug Class

Breast Feeding

Lactation

Complementary Therapies

Galactogogues

Phytotherapy

Plants, Medicinal