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Sulpiride

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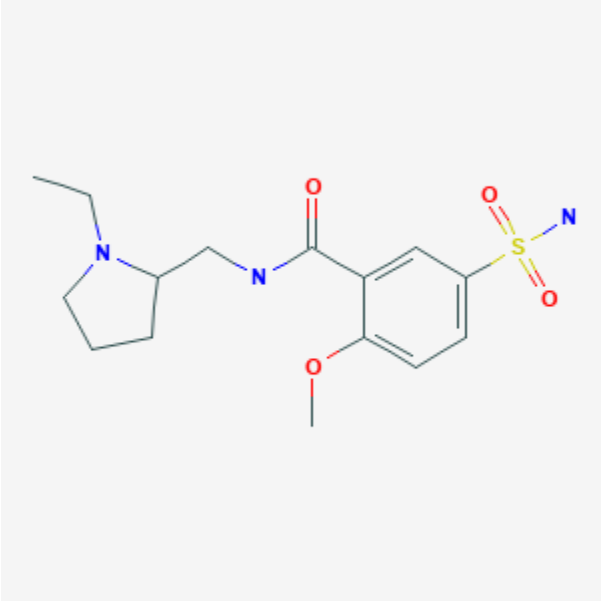

Drug Levels and Effects

Summary of Use during Lactation

Sulpiride is not approved for marketing in the United States by the U.S. Food and Drug Administration, but is used as a psychotherapeutic agent and galactogogue in other countries. Sulpiride increases serum prolactin, but its clinical value in increasing milk supply is questionable. In a study that enrolled only mothers with documented low milk production a few weeks postpartum, sulpiride was effective in increasing milk volume, but it was only more effective than placebo in avoiding supplementation in those with no initial milk production. Galactogogues should never replace evaluation and counseling on modifiable factors that affect milk production. [1] If mothers are provided instruction in good breastfeeding technique and breastfeed frequently, sulpiride is unlikely to provide additional benefit. Whether sulpiride has any benefit as a galactogogue in women who continue to have insufficient milk production after nursing technique and frequency have been optimized has not been studied adequately.

Sulpiride is excreted into breastmilk in rather large amounts, far above the accepted value of 10% of the maternal weight-adjusted dosage in some cases, but blood concentrations in breastfed infants have not been evaluated. Two studies found no adverse effects in breastfed infants whose mothers were treated with sulpiride for 2 to 4 weeks as a galactogogue.

Postpartum mothers are at a relatively high risk for postpartum depression and sulpiride can cause depression as a side effect. Therefore, sulpiride should probably be avoided in women with a history of major depression and not used for prolonged periods in any mothers during this time of high susceptibility. Tiredness occurred occasionally and cases of headache and leg edema have also been reported in nursing mothers taking sulpiride as a galactogogue.[2][3]

Drug Levels

Maternal Levels. In a study reported only in abstract form, sulpiride was not detected in milk (study details and assay limit not stated) with maternal dosages of up to 200 mg daily.[4]

Twenty women were taking sulpiride 50 mg twice daily by mouth to enhance milk production. A single milk sample from each woman was taken at 2 hours after the morning dose between the 3rd to the 7th day of therapy. The average milk sulpiride concentration was 970 mcg/L (range 260 to 1970 mcg/L).[5] This translates to an average daily maximum infant dosage of 146 mcg/kg (range 39 to 297 mcg/kg) in the infant or 8.7% (range 2 to 18%) of the weight-adjusted maternal dosage.

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

Effects in Breastfed Infants

In a study of 14 women given sulpiride 50 mg 3 times daily for 4 weeks, no side effects were reported in their breastfed infants.[3]

In a study of 24 nursing mothers who received sulpiride 50 mg 3 times daily for 2 weeks, no side effects were reported in their breastfed infants.[2]

In a study comparing sulpiride to placebo for enhancement of milk production, infant weight gain was greater in the infants of treated women up to day 15, but there was no difference in weight gain between the groups thereafter.[6]

Effects on Lactation and Breastmilk

Sulpiride increases serum prolactin and may cause galactorrhea at a higher rate than other psychotropic drugs.[7][8][9][10] Several studies have been published on the use of sulpiride in enhancing milk supply.[2][3][5][6][7][11][12] Most of the studies have serious design flaws. Although these studies were all placebo controlled, only 3 studies were blinded and randomized.

In one study, 28 women were randomized to sulpiride 50 mg (n = 14) or placebo (n = 14) 3 times daily for 4 weeks. Women were within 4 months postpartum and had identified themselves as having insufficient milk. The two groups were fairly well matched at the initiation of the trial except that mothers in the placebo group had been supplementing for longer than women in the sulpiride group, 33 and 22 days, respectively. Mothers in both groups fed their infants an average of 5.3 times daily. Mothers were given no instruction on breastfeeding technique. Serum prolactin rose in sulpiride-treated patients to about 400 mcg/L and fell slightly in placebo-treated patients. However, neither milk yields at the beginning of the study nor increases in yield showed any relationship to increases in serum prolactin. Infant weight gain was greater in the treated patients at the end of the study (1081 vs 795 g); however, most of the infants in both groups were supplemented, so it is impossible to

tell if the weight gain in the sulpiride group was caused by increased milk production or by the supplementation.[3]

A study of 66 primiparous mothers with normal infants who expressed a desire to breastfeed, received sulpiride 100 mg 3 times daily for the first 4 days postpartum, then 50 mg 3 times daily for the next 86 days. Mothers who received sulpiride maintained elevated baseline serum prolactin levels of 117 to 119 mcg/L throughout the 90-day study period. Mothers taking placebo had a normal drop in serum prolactin from 113 mcg/L on day 1 to 20 mcg/L on day 90; however, on days 4, 15 and 30, their 30-minute postsuckling prolactin levels reached about the same levels as the sulpiride-treated mothers because they had very small increases in prolactin after nursing. At days 60 and 90, women taking placebo had much lower baseline and postsuckling prolactin levels than treated women. Infant weight gain was greater in the infants of treated women up to day 15, but there was no difference between the groups thereafter.[6] This study suffered from a high 38% dropout rate, which makes intent-to-treat analysis unfeasible.

A randomized, double-blind trial studied 60 women who were 25 to 40 days postpartum, 40 with insufficient lactation averaging 293 mL/day and 20 with no milk production at the start of the study. No mention was made of any lactation education given to the subjects before or during the study or the frequency of nursing during the study. Subjects were given l-sulpiride, d-sulpiride or d,l-sulpiride 50 mg twice daily or placebo for 15 days. Milk production increased in all drug groups. All women with insufficient lactation, including those receiving placebo, could avoid supplementation after 6 days of therapy. Women with no milk production at the start who received a drug were able to stop supplementation after 10 to 15 days; those in the placebo group were not able to breastfeed at the end of the study. The authors state that the increased milk production declined progressively after drug discontinuation, but did not provide any data.[7]

Alternate Drugs to Consider

(Galactogogue) Domperidone, Metoclopramide

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Substance Identification

Substance Name

Sulpiride

CAS Registry Number

15676-16-1

Drug Class

Breast Feeding

Lactation

Antipsychotic Agents

Dopamine Antagonists