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Cabergoline

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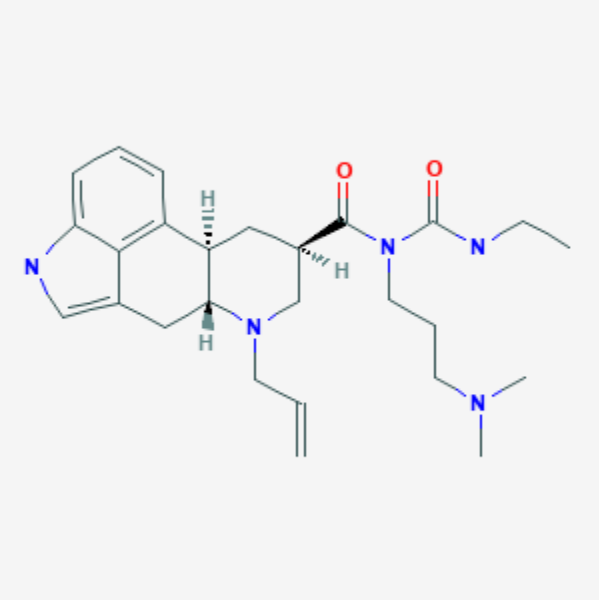

Drug Levels and Effects

Summary of Use during Lactation

Cabergoline is usually not used during breastfeeding because it suppresses lactation. The U.S. Food and Drug Administration considers cabergoline to be not indicated to suppress lactation because the similar drug bromocriptine has caused hypertension, stroke, seizures and psychosis when used for this purpose. Cabergoline's use in other conditions has caused side effects similar to other dopamine agonists, such as bromocriptine. Whether rare cases of severe adverse effects occur with cabergoline as with bromocriptine cannot be determined because of the small number of postpartum patients treated in clinical trials to date. However, limited experience from clinical trials indicates that a single oral dose of 1 mg of cabergoline causes fewer side effects (usually headache, dizziness and nausea) than 14 days of bromocriptine and is at least as effective when used to suppress unwanted lactation. In one review, slight blood pressure lowering was of no clinical importance.[1] Some experts recommend cabergoline as a safer alternative to bromocriptine for lactation suppression, but others do not.[2][3]

[4][5] The disadvantage of cabergoline is that it has a half-life of about 68 hours, which means that any adverse effects will persist for a prolonged period of time. Women treated with cabergoline for pituitary adenomas who become pregnant can breastfed their infants with no apparent risk of recurrence. A treatment scheme has been reported for mothers with hypergalactia that uses low doses of cabergoline to decrease milk supply.[6]

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.

Effects in Breastfed Infants

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

Effects on Lactation and Breastmilk

Seventeen women who did not wish to breastfeed received a placebo or a single oral dose of cabergoline 400 mcg or 600 mcg on day 2 or 3 postpartum. Use of other lactation suppressing measures (e.g., breast binding, lack of nipple stimulation) was not mentioned. Blood samples were taken periodically over the next 96 hours. In the 7 women who received 400 mcg, plasma prolactin levels were decreased at 24 and 48 hours, but 4 developed breast engorgement. In the 5 women who received 600 mcg, plasma prolactin levels were decreased by 12 hours and persisted up to 96 hours and none developed breast engorgement. Some women had minor decreases in blood pressure, but no other adverse effects were reported.[7]

Thirty-two women who did not wish to breastfeed were given placebo or cabergoline 400, 600 or 800 mcg within 24 hours after delivery in a double-blind trial. Use of other lactation suppressing measures (e.g., breast binding, lack of nipple stimulation) was not mentioned. Lactation was prevented in 4 of 8 women who received the 400 mcg dose and all women who received the 600 or 800 mcg dose. Only 1 of 8 women receiving placebo had cessation of lactation by day 14 postpartum. Serum prolactin levels collected on days 2, 3 and 4 of treatment were decreased significantly in all women who received cabergoline, but the decreases were not statistically different among the various doses.[8]

A prospective, randomized, double-blinded study compared the effects of a single dose of cabergoline 0.5, 0.75 or 1 mg in 40 women each and to 20 women who received a placebo. The drug was given in the first 24 hours postpartum and use of other lactation suppressing measures (e.g., breast binding, lack of nipple stimulation) was not mentioned. The adequacy of lactation suppression on day 14 postpartum was dose-related, with excellent results in 18 patients who receive 0.5 mg, 28 who received 0.75 mg and 36 who received 1 mg. Serum prolactin levels collected during 13 days of treatment were decreased significantly in all women who received cabergoline, but the decreases were not statistically different among the various doses. Adverse effects included occasional dizziness and headache between days 1 and 3 after the dose.[9]

In a single-blind trial, 36 women were given either a single oral dose of cabergoline 1 mg or oral bromocriptine 2.5 mg twice daily for 14 days, starting about 50 hours after cesarean section. Use of other lactation suppressing measures (e.g., breast binding, lack of nipple stimulation) was not mentioned. Another 13 women who were breastfeeding after cesarean section served as controls. Both cabergoline and bromocriptine suppressed baseline serum prolactin by about 90% compared to baseline and control women within 3 days; this persisted at least through day 7, but somewhat rebounded by day 14. Suppression of lactation as measured by milk secretion, tenderness, and engorgement was equal between the 2 treatment groups. Lactation suppression was complete in 17 of 18 women who received cabergoline and 16 of 18 women who received bromocriptine, although the response was more rapid with cabergoline. Adverse events from cabergoline were fewer in number than with bromocriptine and consisted of occasional headache lasting 2 days, dizziness, and vomiting.[10]

A well-designed and evaluated double-blind study compared oral cabergoline 1 mg in a single dose (n = 136) to oral bromocriptine 2.5 mg twice daily for 14 days (n = 136) in women within 27 hours postpartum. Some women in each group (cabergoline n = 18; bromocriptine n = 16) received an ergot alkaloid or oral contraceptive postpartum. Symptoms of milk production and engorgement were recorded by the women and serum prolactin levels were measured on 3 occasions during the first 2 to 3 weeks postpartum. Cabergoline was at least as effective as bromocriptine, with complete success in 78% of cabergoline patients and 69% of bromocriptine patients. The rate of rebound lactation was much higher in bromocriptine patients (24%) than in cabergoline patients (5%). Serum prolactin was suppressed in both groups, but rebound was more common with bromocriptine on days 15 and 21. Adverse effects were numerically, but not statistically less frequent in cabergoline patients, with the most frequent being dizziness, headache, nausea and epigastric pain.[11]

Cabergoline was evaluated for lactation suppression in a prospective, but nonrandomized, unblinded trial. Women who were within 24 hours postpartum were given a single 1 mg dose (n = 54); those who were beyond 24 hours were given 0.25 mg twice daily for 2 days (n = 46). Only composite results were given for the entire group of 100 women. Mean serum prolactin dropped from 181.4 mcg/L (range 153 to 213 mcg/L) on the first day to 12.5 mcg/L (range 0.9 to 37 mcg/L) on day 4, and 18.2 mcg/L (range 2 to 36.2 mcg/L) on day 14 after the dose. Lactation was completely inhibited in 92% of women; 8 women required a second doses of 1 mg to inhibit lactation. Twenty-six percent of women had side effects such as dizziness, headache, nausea and abdominal pain. In 4% of women, side effects were severe enough to require symptomatic treatment.[7][12]

In a prospective, nonrandomized, unblinded trial, 43 women who underwent a second trimester abortion were given cabergoline 1 mg orally to suppress lactation. A single dose was effective in 88% of women.[13]

A randomized, nonblinded trial compared cabergoline 0.5 mg (n = 80) and 1 mg (n = 80) orally in a single dose given at an unstated time in the early postpartum period. The 1 mg dose was more effective in suppressing lactation than the 0.5 mg dose. Headache and nausea were the most common adverse effects.[14]

A follow-up survey was conducted on 91 women who became pregnant after treatment with cabergoline for hyperprolactinemia from pituitary adenomas. Eighty-eight patient breastfed their infants, 35 for less than 2 months and 56 for 2 to 6 months. No patients were restarted on cabergoline after pregnancy. At 3 and 12 months after pregnancy, serum prolactin was slightly higher than prepregnancy levels, but by 60 months postpartum, prolactin levels were lower than prepregnancy levels. Mothers who nursed for more than 2 months had lower serum prolactin at 60 months after cessation of breastfeeding than those who breastfed for less than 2 months. The authors concluded that breastfeeding does not increase the risk of recurrence of hyperprolactinemia.[15]

Alternate Drugs to Consider

(Hyperprolactinemia) Bromocriptine

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Substance Identification

Substance Name

Cabergoline

CAS Registry Number

81409-90-7

Drug Class

Breast Feeding

Lactation

Antiparkinson Agents

Dopamine Agonists