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Progesterone

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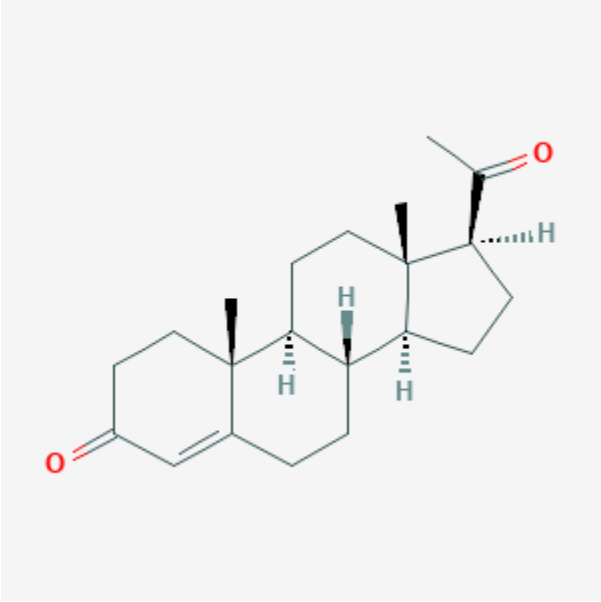

Drug Levels and Effects

Summary of Use during Lactation

Release from the progesterone-releasing intrauterine device available in the United States is 65 mcg/day or only 0.65% of the dose released from most of the devices reported in the literature. Because of the low levels of progesterone in breastmilk, even with the high-dose products, amounts ingested by the infant are small and would not be expected to cause any adverse effects in breastfed infants. The progesterone vaginal ring available in some countries produces maternal blood levels that are lower than those of ovulating women.[1] Most studies indicate that progesterone is not detrimental to milk production or duration of nursing.[2][3] No special precautions appear to be required.

In Russia, a progesterone gel (Progestogel - Besins Healthcare; not available in the US) has been used topically as a one-time application to the breasts to treat postpartum breast engorgement when more conservative measures have failed.[4] A subsequent study failed to detect any decrease in breast hardness 20 minutes after application of

progesterone gel in mothers with engorgement.[5] The safety and efficacy of this use have not been well studied and the manufacturer of Progestogel recommends avoiding its use during lactation.

Drug Levels

Maternal Levels. Women who received 6 subdermal implants containing 100 mg each of progesterone between days 30 to 35 postpartum for contraception had milk progesterone levels measured. Milk progesterone levels were 5.7 mcg/L in 6 women at 3 to 4 months postpartum and 6.3 mcg/L in 7 women at 9 to 12 months postpartum. By comparison, 9 women who received a Copper T intrauterine device had negligible progesterone levels. The authors estimated that infants would receive about 5 mcg of progesterone daily through breastmilk.[6][7]

Infant Levels. Women received 6 subdermal implants containing 100 mg each of progesterone between days 30 to 35 postpartum for contraception. A metabolite of progesterone, pregnane-3-glucuronide, was measured in the urine of their infants. At 3 to 4 months (n = 9) and 9 to 12 months (n = 7) postpartum, urine metabolite levels were 6.3 mcg/L and 15.7 mcg/L, respectively. These values were not significantly different from those of infants whose mothers were using a Copper T intrauterine device.[6][7]

Effects in Breastfed Infants

Eighty-four women had 6 subdermal implants containing 100 mg each of progesterone inserted between days 30 to 35 postpartum as a contraceptive. Compared to women who received either a placebo or a Copper T intrauterine device, there were no differences in the growth rates of their infants over the first 6 months postpartum.[8]

One hundred ninety-two mothers who received 6 subdermal implants containing 100 mg each of progesterone inserted on postpartum day 60 as a contraceptive. The weight gain of 60 infants who were exclusively breastfed for 6 months was compared to that of infants whose mothers received either placebo (n = 68 at day 30) or a Copper T (n = 64 at day 30 and n = 49 at day 60) intrauterine device. No differences were found in the average weight gains among the 3 groups of infants at 6 months of age.[9]

Vaginal rings that released progesterone were inserted at about 60 days postpartum in 128 women. The 2 types of rings released progesterone either 7.5 mg daily decreasing to 4.5 mg at 90 days or 15 mg daily decreasing to 7 mg daily at 90 days. Over the first 12 months postpartum, no differences in weight gain were found between the exclusively breastfed infants of mothers who received the progesterone rings and control mothers who received a Copper T intrauterine device for contraception.[10]

One hundred twenty breastfeeding women used a vaginal ring that released about 10 mg daily of progesterone for 90 days, starting during weeks 5 to 7 postpartum. No differences were found in the growth of breastfed infants or in developmental milestones compared to the normal population values.[11]

One hundred eighty-seven breastfeeding women used a vaginal ring that released about 10 mg daily of progesterone, starting at about day 57 postpartum. No differences were found in weight gain during the first 6 months of use compared to infants whose mothers received either a Copper T intrauterine device, an oral progestin-only contraceptive or levonorgestrel implant.[12]

A study comparing 100 women who received vaginal ring that released about 10 mg daily of progesterone to those who received a Copper T intrauterine device between days 29 and 64 postpartum found no differences in weight gain of their breastfed infants over the first year postpartum.[13]

Two hundred eighty-five women who received a vaginal ring that released about 10 mg daily of progesterone were compared to 262 women who received a Copper T intrauterine device beginning between weeks 5 and 9

postpartum. No differences in the weight gain of breastfed infants were seen between the 2 groups during the 14-month observation period.[14]

A transgender woman took and spironolactone 50 mg twice daily to suppress testosterone, domperidone 10 mg three times daily, increasing to 20 mg four times daily, oral micronized progesterone 200 mg daily and oral estradiol to 8 mg daily and pumped her breasts 6 times daily to induce lactation. After 3 months of treatment, estradiol regimen was changed to a 0.025 mg daily patch and the progesterone dose was lowered to 100 mg daily. Two weeks later, she began exclusively breastfeeding the newborn of her partner. Breastfeeding was exclusive for 6 weeks, during which the infant's growth, development and bowel habits were normal. The patient continued to partially breastfeed the infant for at least 6 months.[15]

Effects on Lactation and Breastmilk

Eighty-four women had 6 subdermal implants containing 100 mg each of progesterone inserted between days 30 to 35 postpartum as a contraceptive. Compared to women who received either a placebo or a Copper T intrauterine device, no difference was found in the breastfeeding rates during the first 9 months postpartum. At 1 year postpartum, more women in the Copper T group were breastfeeding than in the progesterone or placebo groups.[8]

Vaginal rings that released progesterone were inserted at about 60 days postpartum in 246 women. The 3 types of rings released progesterone either 5, 10 or 15 mg daily. Control women received a Copper T intrauterine device. At 6 and 12 months postpartum there was no significant difference in the percentage of infants who were breastfed between the progesterone and Copper T groups.[16]

One hundred twenty breastfeeding women used a vaginal ring that released about 10 mg daily of progesterone, starting during weeks 5 to 7 postpartum. The rate of weaning was greater in the progesterone ring group than in groups of women who received levonorgestrel or norethindrone implants for postpartum contraception.[11]

In a multicenter study, 802 women who received a vaginal ring that released about 10 mg daily of progesterone were compared to 734 women who received a Copper T intrauterine device beginning at day 29 to 63 postpartum. No differences were found in the rate of breastfeeding between the 2 groups over the first year postpartum.[17]

Two hundred eighty-five women who received a vaginal ring that released about 10 mg daily of progesterone were compared to 262 women who received a Copper T intrauterine device beginning between weeks 5 and 9 postpartum. No differences in the breastfeeding rates were seen between the 2 groups during the 14-month observation period.[14]

An observational study followed 192 women who used a vaginal ring that released 10 mg of progesterone daily beginning between days 54 and 64 postpartum. All subjects used the vaginal ring for at least 4 months; 90% were still using it at 6 months and 73% were using it at 9 months postpartum. The duration of breastfeeding and infant growth were similar to reference groups.[18]

A double-blind placebo-controlled trial randomized 46 postpartum women who were abstinent former smokers to oral micronized progesterone 200 mg twice a day or placebo for 4 weeks to assess smoking abstinence rates. Entry into the study occurred only after breastfeeding was well established. No statistical difference was found in the number of days of breastfeeding between the groups.[19]

Alternate Drugs to Consider

(Contraception) Etonogestrel, Intrauterine Copper Contraceptive, Levonorgestrel Implant, Intrauterine Levonorgestrel, Medroxyprogesterone Acetate

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Substance Identification

Substance Name

Progesterone

CAS Registry Number

57-83-0

Drug Class

Breast Feeding

Lactation

Hormones

Progesterone Congeners