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Somatropin

Revised: October 31, 2018.

CASRN: 12629-01-5

Drug Levels and Effects

Summary of Use during Lactation

Limited data indicate that exogenous somatropin does not increase normal breastmilk concentrations of growth hormone and that no adverse effects are experienced by the breastfed infants of mothers who receive somatropin. Small studies by one group of investigators found that milk output increases from 19% to 36% after a 7-day course of somatropin. Because mothers were not given extensive breastfeeding support in these studies, the usefulness of the drug as a galactogogue in mothers given adequate breastfeeding support is not known. Galactogogues should never replace evaluation and counseling on modifiable factors that affect milk production. [1]

Based on theoretical considerations, the manufacturer of Zomacton 5 mg recommends avoiding the use of the diluent, which contains benzyl alcohol, for lactating women. Instead use preservative-free normal saline as a diluent and discard any remaining drug.

Drug Levels

Maternal Levels. Eight lactating women were given somatropin 0.1 international units/kg daily subcutaneously for 7 days. There was no difference in human growth hormone concentrations in breastmilk before and 1 day after finishing the course of somatoropin. Milk concentration of insulin-like growth factor-1 (IGF-I) increased by 91% from 1.04 to 1.99 mcg/L over the same time period.[2] In a study of similar design, the same group of investigators reported an increase of 134% in IGF-I over the study period. There was no change in milk concentrations of IGF-II during the study.[3]

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

Effects in Breastfed Infants

Among 34 infants in 3 studies who were breastfed during maternal use of subcutaneous somatropin for 7 days during lactation, none were reported to have adverse reactions to the drug. Dosages were 0.05 (n = 5), 0.1 (n = 13) or 0.2 (n = 16) international units daily.[2][4][5]

Effects on Lactation and Breastmilk

In a double-blind study, normal, lactating women were given somatropin 0.1 international units/kg daily subcutaneously for 7 days or placebo. The 8 women given somatropin increased their average milk output by 157 mL daily from the baseline of 835 mL daily. Placebo-treated patients experienced an increase from 855 mL daily to 955 mL daily. The difference in increase between the two groups was statistically significant. Milk content did not change with therapy.[2]

Ten mothers of premature infants born at an average of 30.6 weeks gestation (range 26 to 34 weeks) were given subcutaneous somatropin to increase their milk supply at an average of 39.7 days postpartum. The dosage was 0.2 international units daily, up to a maximum of 16 international units daily, for 7 days. The amount of milk produced on day 8 was compared to the average amount extracted on the 2 days prior to therapy. Average milk production increased from 139 mL daily to 175 mL daily compared to a statistically nonsignificant increase from 93 mL daily to 102 mL daily in the placebo group. Many of the mothers in the placebo group, but none in the somatropin group, had decreases in production during the study.[5] The differences in baseline milk production between the 2 groups might have affected the response to somatropin and the study did not report the changes, if any, in the proportion of infant nutrition from breastmilk.

The same group studied 16 lactating mothers with normal healthy infants; 5 of the women were having lactational problems. Women received either subcutaneous somatropin 0.05, 0.1 or 0.2 international units daily for 7 days. The two low-dose groups (n = 10) had a 4.7% increase in their milk output; mothers in the high-dose group (n = 6) increased their milk output by 36% from the baseline of 297 mL daily output. Three of the mothers who received the higher dose were able to completely or nearly completely breastfeed their infants.[4]

None of the above studies reported providing mothers with information on breastfeeding technique or any other type of breastfeeding support.

In a study designed to determine the genetic effects of growth hormone administration, 5 nursing mothers were given somatropin (Nortitropin) 0.1 mg/kg by subcutaneous injection once daily at about 800 am for 3 days. No difference was found in the average suckling-induced serum prolactin levels on day 1 (baseline) and day 4. Average milk volume did not change over the 4-day study period. The study found that DNA synthesis and cell cycle genes were induced, but no changes were observed in the expression of milk synthesis genes. The authors speculated that the duration of the study might have been too short to observe induction of milk synthesis genes.[6]

References

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Substance Identification

Substance Name

Somatropin

CAS Registry Number

12629-01-5

Drug Class

Breast Feeding

Lactation

Galactogogues

Human Growth Hormone