Lactation subsection: Overview

Risk Summary

For drugs that are not systemically absorbed, there is a standard statement that states that maternal use is not expected to result in infant exposure.

For drugs that are systemically absorbed, the risk summary must describe the following information or state that it is not available:

- Effects of drug on milk production

- Presence of drug in human milk
  - If drug not detected, state limits of assay.
  - If drug is detected, provide drug concentration in milk and estimated infant daily dose (actual and compared to pediatric or maternal doses)
  - Effects of the drug on the breast-fed child

- If data shows that the drug does not affect the quantity and quality of breast milk and there is reasonable certainty that either the drug is not detectable in breast milk or will not adversely affect the breast fed child, then state:
  - "The use of (name of drug) is compatible with breastfeeding."

Clinical Considerations

This section must provide, when available, information on:

- Ways to minimize exposure of the breast-fed infant to the drug
- Dosing adjustments during lactation

Data

This section must provide an overview of the data that are the basis for information in the risk summary and clinical considerations.

Lactation subsection: Labeling samples

1. <u>Drug for which no data are available:</u>

<u>Risk Summary</u>
No studies have been conducted to assess ALPHAZINE's impact on milk production, its presence in breast milk or its effects on the breast-fed child.

<u>Clinical Considerations</u>
Other medical therapies are available for the treatment of maternal hypertension.

<u>Data</u>
No data available.

2. <u>Drug for which pharmacologic class information is available, but no human data are available:</u>

<u>Risk Summary</u>
No studies have been conducted to assess THETAM's effect on milk production, its presence in breast milk, or its effects on the breast-fed child. Based on experience with other products in this class, maternal THETAM use has the potential to cause neutropenia in the breast-fed child. Because of the potential for neutropenia in the breast-fed child, a decision should be made whether to discontinue breast-feeding or discontinue using THETAM.

<u>Clinical Considerations</u>
Other medical therapies are available for the treatment of maternal fungal infection.

<u>Data</u>
No data available.

3. <u>Drug for which human data are available:</u>

<u>Risk Summary</u>
GAMMATOL is secreted in human milk. At a maternal dose of 400 mg daily, the average milk concentration, collected over 24 hours after dosing, was 10 mcg/mL which is lower than maternal serum drug concentrations at steady state. Based on an average milk consumption of 150 mL/kg/day, a 2-month-old infant would consume approximately 6 mg/day of GAMMATOL via breast milk, which is approximately 1.3% of the maternal dose. No studies have been performed to assess infant absorption and exposure to GAMMATOL from breast milk. No studies have been performed to assess the impact of GAMMATOL on milk production or its effects on the breast-fed child.

Clinical Considerations
Because GAMMATOL is taken once daily, mothers can reduce infant exposure by taking their GAMMATOL dose immediately after breast-feeding at the time of day when feedings are less frequent.

Data
A lactation study was performed in 30 women who were two months postpartum and exclusively breast-feeding their infants. All women enrolled in the study were taking a 400 mg single dose of GAMMATOL daily. Breast milk samples were collected from each breast at the beginning and end of each feeding for 24 hours after a GAMMATOL dose. An average maximum milk concentration of 20 mcg/mL occurred 3 hours after dosing and drug concentrations in milk rapidly declined over the next 12 hours. The average milk concentration was 10 mcg/mL. No drug was detectable in milk samples obtained 36 hours or later after dosing. No data are available to assess the impact of GAMMATOL on milk production or its effects on the breast-fed child.