



Drugs and Lactation Database (LactMed) - About Dietary Supplements

Dietary supplement manufacturers or dietary ingredient suppliers are not required to test ingredients for safety in animals, or for safety or efficacy in women who are breastfeeding. Much of the available safety information comes from historical use and observational data.

Although the US Food and Drug Administration now requires dietary supplement manufacturers to report serious adverse events related to their products, only limited data involve lactation. Much post-marketing surveillance goes unreported. Reports that appear in the literature may be missing important information, such as testing for purity or contaminants.

One of the major limitations in reporting on dietary supplements is that the formulation and method of preparation of a product with a given trade name may change over time. For example, a combination product containing fenugreek may not contain the same ingredients today as it did a year ago. Trendy ingredients such as acai berry, pomegranate, etc. are often added and removed depending upon whether they are in vogue at any given time.

Although some individual dietary supplement ingredients may have been tested for their ability to pass into breastmilk, extrapolating this information to commercial products is problematic, because such products often differ in their composition and content of the same ingredients.

Many commercially available dietary supplements contain combinations of ingredients, such as herbs, vitamins, minerals, and omega-3 fatty acids, which make safety and efficacy assessments during breastfeeding challenging. In such combination products, it is difficult to pinpoint which one or more ingredients account for an adverse outcome.

Herbal extraction and formulation methods may vary over time, and result in products with variable amounts and proportions of ingredients.

For supplements containing an herb, manufacturers must be alert to test for heavy metals (e.g., cadmium, lead, mercury, arsenic) derived from the soil, and limit their levels. The presence of bacteria and fungi should also be minimized in herbal products used during lactation.

Disclaimer: Information presented in this database is not meant as a substitute for professional judgment. You should consult your healthcare provider for breastfeeding advice related to your particular situation. The U.S. government does not warrant or assume any liability or responsibility for the accuracy or completeness of the information on this Site.

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