

U.S. National Library of Medicine National Center for Biotechnology Information **NLM Citation:** Drugs and Lactation Database (LactMed®) [Internet]. Bethesda (MD): National Institute of Child Health and Human Development; 2006-. Nivolumab. [Updated 2023 Nov 15]. **Bookshelf URL:** https://www.ncbi.nlm.nih.gov/books/



Nivolumab

Revised: November 15, 2023.

CASRN: 946414-94-4

Drug Levels and Effects

Summary of Use during Lactation

Nivolumab milk levels in one mother were unexpectedly high and appeared to accumulate with repeated doses, possibly because it is an IgG₄ antibody rather than the more typical IgG₁ for other monoclonal antibodies It is also likely to be partially destroyed in the infant's gastrointestinal tract and absorption by the infant is probably minimal.[1] However, until more data become available, nivolumab should probably be avoided during breastfeeding, especially while nursing a newborn or preterm infant. The manufacturer recommends that breastfeeding be discontinued during nivolumab therapy and for 5 months after the last dose of the drug.

Drug Levels

Maternal Levels. A mother with melanoma was started on intravenous nivolumab 480 mg every four weeks at 6 weeks post-partum. Seventy-two breast milk samples were collected over a 34-day period during the first and second cycles of therapy. A peak concentration of 157 mcg/L occurred on day 3 after the first dose, then after a decline in concentrations another increase in concentrations started at day 7 reaching a peak concentration of 503 mcg/L on day 13. The milk concentration at the time of the second dose on day 27 was about 175 mcg/L and the peak milk concentration of nivolumab at 7 days after the second dose was higher after the second dose. The authors speculated that nivolumab accumulation in milk could continue because of its long half-life.[2]

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

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

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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References

- 1. Anderson PO. Monoclonal antibodies during breastfeeding. Breastfeed Med 2021;16:591-3. PubMed PMID: 33956488.
- 2. de Jong K, Damoiseaux D, Pluim D, et al. High accumulation of nivolumab in human breast milk: A case report. Biomed Pharmacother 2023;166:115354. PubMed PMID: 37625324.

Substance Identification

Substance Name

Nivolumab

CAS Registry Number

946414-94-4

Drug Class

Breast Feeding Lactation Milk, Human Antineoplastic Agents Biological Response Modifiers Immunologic Adjuvants Immune Checkpoint Inhibitors Antibodies, Monoclonal