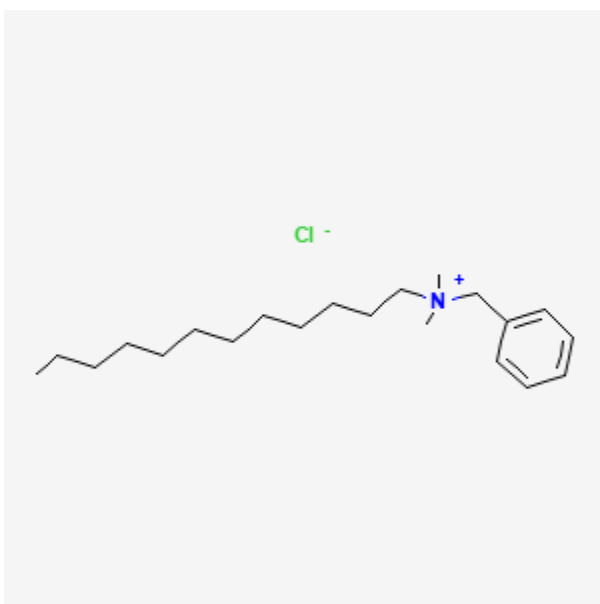




## Benzalkonium Chloride

Revised: September 19, 2022.

CASRN: 8001-54-5



## Drug Levels and Effects

### Summary of Use during Lactation

Topical maternal application of benzalkonium chloride or benzethonium chloride or their presence as a preservative in pharmaceuticals would not be expected to cause any adverse effects in breastfed infants. Household disinfecting sprays and wipes contribute to the benzalkonium chloride content of milk. The effects of long-term exposure of the infant to low levels in milk is not known.

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## Drug Levels

*Maternal Levels.* Four women using tampons containing benzalkonium chloride 60 mg provided breast milk samples 15 min prior to tampon application and 3 and 24 h after application. Benzalkonium chloride was not detected in the blood or breastmilk in any of the four subjects using HPLC analysis (assay limit not stated).[1]

A study of 48 women in the Seattle, Washington area ranging in age from 24 to 42 years of age who were breastfeeding their first child manually extracted milk samples for analysis. Milk samples were collected prior to the COVID-19 pandemic. Ninety milk samples containing benzalkonium compounds with alkyl chain lengths ranging from C10 to C18 had a mean total benzalkonium concentration of 1.2 mcg/L. Quaternary ammonium compounds (QACs, including alkyltrimethyl ammonium compounds) were found in breastmilk with at least one QAC found in each sample and 7 QACs detected in more than half of the samples. The highest concentrations of benzalkonium chloride components were of C12 at 0.51 mcg/L and C14 at 0.56 mcg/L. Higher QAC levels in breastmilk were found in mothers who used QAC-containing disinfecting products (especially sprays) and disinfected more often. The authors estimated that fully breastfed infants would receive average daily benzalkonium chloride intake of 138 ng/kg under 1 month of age, 128 ng/kg from 1 to 3 months of age, 102 ng/kg from 3 to 6 months of age and 77 ng/kg between 6 and 12 months of age (nonexclusive breastfeeding), based on variations in milk intake during each time period.[2]

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

## Effects in Breastfed Infants

A study in Japan randomized 80 consecutive term patients into 4 groups who received either povidone-iodine or benzethonium chloride as a skin disinfectant before delivery and one of these for postpartum vaginal lacerations. Prepartum doses were about 7 mL and postpartum doses were about 0.5 mL of solution. Infant thyrotropin levels were elevated in the infants whose mothers received topical povidone-iodine pre- and postpartum compared to infants whose mothers received benzethonium chloride.[3]

## Effects on Lactation and Breastmilk

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

## Alternate Drugs to Consider

Chlorhexidine

## References

1. Johnson W Jr. Final report on the safety assessment of benzalkonium chloride. J Am Coll Toxicol. 1989;8:589–625.
2. Zheng G, Schreder E, Sathyanarayana S, et al. The first detection of quaternary ammonium compounds in breast milk: Implications for early-life exposure. J Expo Sci Environ Epidemiol. 2022;32:682–8. PubMed PMID: 35437305.
3. Koga Y, Sano H, Kikukawa Y, et al. Affect on neonatal thyroid function of povidone-iodine used on mothers during perinatal period. J Obstet Gynaecol (Tokyo). 1995;21:581–5. PubMed PMID: 8640469.

## Substance Identification

### Substance Name

Benzalkonium Chloride

## **CAS Registry Number**

8001-54-5

## **Drug Class**

Breast Feeding

Lactation

Milk, Human

Anti-Infective Agents, Local

Antibacterial Agents

Detergents

Preservatives, Pharmaceutical