

Q&A 266.4

Can breastfeeding mothers take ibuprofen?

Prepared by UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals
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Date prepared: 24 July 2015

Background

Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) used to relieve pain and inflammation in rheumatic disease and other musculoskeletal disorders. Ibuprofen is also used for mild to moderate pain including dysmenorrhoea, postoperative analgesia, dental pain and migraine (1). It can also be given to infants aged 1–3 months at a dose of 5 mg/kg body weight 3–4 times daily for pain, inflammation of soft-tissue injuries, and pyrexia (2), although this is off-label under 3 months. Ibuprofen can be prescribed, but is widely available as an over-the-counter (OTC) medicine.

The information provided below only applies to full term and healthy infants. In general, medicines should be avoided by mothers breastfeeding premature or low birth weight infants, or infants who have underlying medical conditions. In such cases further advice should be sought.

Answer

In two studies where ibuprofen was administered to lactating women, the drug was not detected in breast milk. In one study, one woman took ibuprofen 400 mg twice daily for three weeks for post-partum onset of arthritis. Although ibuprofen and its metabolites were detected in the mother's serum, no measurable ibuprofen was detected in breast milk (*lower limit of assay sensitivity 0.5 micrograms/mL*) (3). In a second study, twelve women were given 400 mg six hourly for five doses for pain after Caesarean section. Although normal serum levels of ibuprofen were found in the mothers, no measurable ibuprofen was detected in breast milk (*lower limit of assay sensitivity 1.0 micrograms/mL*) (4). Infants were not breastfeeding in either study.

In a further single case study, a lactating woman was given six 400 mg tablets of ibuprofen over 42 hours for postoperative pain (5). Ibuprofen was detected in breast milk using a more sensitive analytical method than used in the previous two studies (*lower limit of assay sensitivity 2.5 nanograms/mL*). Very low levels of ibuprofen were detected in milk, ranging from 13 nanograms/mL 30 minutes after ingestion of the first tablet, to 181 nanograms/mL after 20 hours with a calculated milk/plasma ratio of <0.01. These levels approximated to an infant intake of 100 micrograms in 24 hours. This will be an insignificant quantity if ingested by a breastfeeding infant.

In a study to determine the relative infant dose of ibuprofen through breastfeeding, 13 breastfeeding mothers who had taken at least three 200 mg ibuprofen tablets at regular intervals at least 7 days after delivery were included (6). Samples were taken from pumped milk 1.5 to 8 hours after the third dose of ibuprofen. In addition, two maternal blood samples were taken (30 minutes to 2 hours, and 4 to 6 hours) post the third ibuprofen dose. The mean concentration of ibuprofen was 361 micrograms/L in milk and 15.5 mg/L in the serum. The milk plasma ratio was 0.025. The infants received a mean dose of 68 micrograms/kg/day (range 8–262 micrograms/kg/day) of ibuprofen from breast milk, which is significantly below the therapeutic dose of 15–20mg/kg/day recommended for infants aged 1–3 months (2). In addition, the relative infant dose was estimated to be 0.38% (range 0.04–1.53%) of the weight-adjusted daily maternal dose. This study also confirmed the hypothesis that the amount of drug in mature milk would decrease as the duration of lactation increased, because the amount of protein in milk decreases over time (6) and ibuprofen is highly (>99%) protein bound (7).

In a follow-up study by the same authors, it was found that two polymorphisms of CYP2C9, a major contributor to ibuprofen metabolism, were still associated with low ibuprofen exposure via breast milk, and a low relative infant dose of less than 1%. This suggests that ibuprofen can be considered as a safe drug for all infants during breastfeeding, despite mothers who carry these polymorphisms (8).

In a prospective, telephone follow-up study, no side effects were noted in 21 breastfed infants whose mothers were taking ibuprofen (9).

The plasma half-life of ibuprofen is very short, with a range of 1.8–2.5 hours (7) giving less risk of accumulation.

Breastfeeding is considered safe if the mother is taking ibuprofen since the quantity of ibuprofen that passes into the milk is insignificant (7,10,11) relative to the infant dose of 5 mg/kg 3–4 times daily (2).

Ibuprofen is normally formulated as ibuprofen base. Some OTC preparations are formulated as the lysine salt. Lysine is a naturally occurring essential amino acid. Although there are no specific data relating to ibuprofen lysine in breastfeeding, it is considered to be as safe as ibuprofen base (11).

Summary

- ◆ Ibuprofen is considered safe for breastfeeding infants as only very small quantities appear to be excreted into breast milk after maternal ingestion. Further, it is considered to be one of the analgesics of choice in breastfeeding mothers.
- ◆ Further expert help must be sought if the infant is pre-term, low birth weight or has an underlying medical condition.

Limitations

Evidence relating to the excretion of ibuprofen in breast milk is scant and mostly relatively old. However, this is offset by the pharmacodynamic and pharmacokinetic properties of ibuprofen and its extensive use, both prescribed and over-the-counter, since its launch in the UK in 1969 without any reports of adverse effects in breastfed infants.

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Date Prepared

24 July 2015

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Date of check

29 July 2015

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