

Can breastfeeding mothers take paracetamol?

Prepared by UK Medicines Information ([UKMi](http://www.ukmi.nhs.uk)) pharmacists for NHS healthcare professionals
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 Date prepared: 20 February 2015

Background

Paracetamol is a non-opioid analgesic, similar in efficacy to aspirin, but with no anti-inflammatory action (1). Paracetamol can be taken to relieve mild to moderate pain and pyrexia (1). It can be prescribed, but is normally purchased as an over-the-counter medicine. Paracetamol can also be given therapeutically to infants from birth (including premature infants from 28 weeks postmenstrual age) at a dose from 10–15 mg/kg body weight every 8–12 hours for pain and pyrexia, including post-immunisation pyrexia (2).

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

Answer

Despite paracetamol being so widely available and used in all age groups for a wide range of pain-associated conditions, direct evidence for its safety in breastfeeding infants is relatively poor. It is largely based on small, uncontrolled studies using only single doses of paracetamol.

In five small studies, a total of 31 mothers received single doses of paracetamol ranging from 500mg to 1g (3–7).

In the first study 11 mothers took 1g paracetamol 3–9 days after delivery. The mean milk paracetamol level from 32 samples was 9 micrograms/ml, with a milk/plasma ratio of 0.2–1.9 (mean 1.0). The maximum daily ingestion of paracetamol by an infant was calculated as 10mg (3).

A second study involved 12 nursing mothers who were given a single 650mg dose of paracetamol. Peak milk levels of 10–15 micrograms/ml were found 1–2 hours after ingestion. With an assumption of 90ml milk consumption every 3 hours, it was calculated that the infant would ingest 0.28–1.51mg (average 0.88mg), equivalent to 0.04–0.23% of a maternal dose (4) *(which we have calculated as equivalent to approximately 3–12.5% of a therapeutic dose in infants assuming a daily milk intake of 150ml/kg body weight)*.

In a further study, 3 lactating women were given a single 500mg dose of paracetamol. Mean peak milk levels 2 hours after the single dose were 27.8 micromol/L (*equivalent to 4.2 micrograms/ml*) with corresponding peak maternal plasma levels of 37.0 micromol/L (*5.6 micrograms/ml*). The mean elimination half-life in both maternal plasma and milk was 2.7 hours. It was calculated that the maximum exposure to the infant would be 2.91 micromol/100ml milk (*4.4 micrograms/ml*) representing less than 0.1% of the maternal dose (5).

The fourth study recruited nursing mothers who received a single dose of 1g paracetamol. The mean area under the milk concentration-time curve was 21.1micrograms/ml, compared to 13.1micrograms/ml for maternal plasma. In seven milk samples, no metabolites of paracetamol were detected. The levels of paracetamol in milk were higher from breasts sampled repeatedly compared to those sampled only once. The mean maximum levels of paracetamol in milk were 10.3 micrograms/ml with average levels of 6.1 micrograms/ml. It

was calculated that an infant feeding once at peak milk levels would ingest 1.85% of a weight-adjusted maternal dose (6).

In a case report, a mother was given 1g paracetamol at bedtime for 2 days, after which a maculopapular rash appeared on the infant's upper trunk and face and disappeared 24 hours after discontinuation of the paracetamol. Two weeks later, the mother was given another 1g dose of paracetamol, and the rash recurred in the infant, of similar type and duration to that previously. Paired milk levels at approximately 2 and 3 hours after the dose were an average of 6.4 and 4.9 micrograms/ml respectively, compared to maternal plasma levels of 8.5 and 9.7 micrograms/ml (7).

In a prospective, telephone follow-up study, no side effects were noted in 43 breastfed infants whose mothers were taking paracetamol (8). Additionally, no adverse effects in breastfed infants were noted whose mothers had been given paracetamol (4) or its prodrug, phenacetin (9).

The method of calculation of the quantity of paracetamol ingested by a breastfeeding infant varied, but all studies showed this to be very low and well below levels expected if infants had been given a therapeutic dose. Assuming a breast milk intake of 150ml/kg body weight/day (10,11), and that the infant breastfed at times coinciding with peak milk levels of paracetamol, it is calculated that an infant would ingest 0.6–1.5mg/kg body weight paracetamol daily. This compares to a minimum therapeutic dose in a pre-term infant of 10–15mg/kg every 8–12 hours (1).

The plasma half life of paracetamol in adults is short at approximately 2 hours (10). In one study, the mean elimination half-life in both maternal plasma and milk was 2.7 hours (5).

Paracetamol is considered to be compatible with breastfeeding and appears to present no significant risk to the infant. The risk of hypersensitivity reactions in the infant due to exposure to low levels of paracetamol or its metabolites is a possibility but does not alter the conclusion that paracetamol is the analgesic of choice in mothers who are breastfeeding their infants (11).

Summary

- ◆ The risk to the breastfed infant of administering paracetamol to its mother is low on the basis that the quantity of drug that passes into milk is very small, representing only a small proportion of a normal therapeutic infant dose, and it also has a relatively short elimination half-life. The balance of evidence suggests that the amounts secreted into breast milk are too small to be hazardous, except the possibility of a hypersensitivity reaction, and that paracetamol should be considered the analgesic of choice during breastfeeding.
- ◆ Further expert advice must be sought if the infant is pre-term, low birth weight or has an underlying medical condition that may affect disposition or excretion of the drug.

Limitations

- Evidence relating to the secretion of paracetamol in breast milk is scant and relatively old. It is based on small population, uncontrolled, single-dose studies. Methodologies for measuring paracetamol levels in breast milk have been varied, so it is not possible to be confident about the amounts appearing in breast milk, although these have been uniformly low. However, this is offset by the pharmacodynamic and pharmacokinetic properties of paracetamol and its extensive use, both prescribed and over-the-counter, since its launch in the UK in 1956, with only one report of a possible hypersensitivity skin reaction in breastfed infants.

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Date Prepared

20 February 2015

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Date of check

29 April 2015

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