

Can breastfeeding mothers take paracetamol or combination paracetamol products?

Prepared by UK Medicines Information ([UKMi](#)) pharmacists for NHS healthcare professionals
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Summary

- ◆ Paracetamol is the painkiller of choice whilst breastfeeding.
- ◆ Very small amounts of paracetamol pass into the breast milk, and these amounts are far below the doses that would normally be given to infants directly.
- ◆ The properties of paracetamol are such that there is no risk of it building up in the infant's system.
- ◆ There have been no adverse effects reported in infants exposed to paracetamol through breastmilk, except for one isolated case report of a hypersensitivity reaction. However, given the length of time that paracetamol has been available on the market, and its widespread use, the risk of such a reaction happening is extremely rare.
- ◆ See the latest NHS advice regarding the use of paracetamol to **manage the symptoms of coronavirus (COVID-19)**: <https://www.nhs.uk/medicines/paracetamol-for-adults/>
- ◆ Paracetamol products are currently in high demand and, therefore a combination product may need to be purchased, for example a product which is used for the treatment of colds and flu. The other ingredients within these products will also need to be considered in terms of suitability for breastfeeding.
- ◆ Other ingredients which paracetamol can be bought in combination with include: codeine, caffeine, diphenhydramine, ibuprofen, phenylephrine, and pseudoephedrine. The safety of these ingredients whilst breastfeeding is also considered within this Q & A.
- ◆ If a combination product is unavoidable, then those containing ibuprofen or caffeine would be the most suitable. See the latest NHS advice regarding the use of ibuprofen to **manage the symptoms of coronavirus (COVID-19)**: <https://www.nhs.uk/medicines/ibuprofen-for-adults/>
- ◆ This guidance applies to infants born full term and healthy. If an infant is unwell, or premature, or the mother is taking multiple medicines, then an individual risk assessment will need to be made.
- ◆ **If a breastfeeding mother is infected with coronavirus (COVID-19) it is still advisable for her to breastfeed her infant since the benefits of breastfeeding outweigh any risk of transmission of the infection. For the latest guidance, see [Public Health England](#).**

Background

Paracetamol is a simple analgesic (painkiller), similar to aspirin and ibuprofen, but with no anti-inflammatory effect (1). It is taken to relieve mild to moderate pain and to reduce a high temperature (fever) (1). It can be prescribed, but it is normally purchased as an over-the-counter medicine. It is available within many combination products.

Breastfeeding mothers may find themselves needing pain relief for a variety of conditions, and therefore advising on suitability in this population is essential.

Amounts in breast milk

Despite paracetamol being widely available and used in all age groups for a number of pain-related conditions, there is still very little published evidence for its use during breastfeeding.

From the 5 small studies which are available (3–7), the method used to calculate the quantity of paracetamol in the breast milk varied. However, all studies showed this to be very low, and well below the doses that would be given to infants directly.

Assuming a breast milk intake of 150mL/kg body weight/day, and using the maximum levels of paracetamol which have been measured in breast milk from these studies, the infant would ingest 0.6–1.5mg/kg paracetamol daily. This is well below the doses which are used in infants directly (20–60mg/kg daily) (2).

Side-effects

In a single case report, a mother was given 1g paracetamol at bedtime for 2 days, after which a maculopapular rash appeared on the infant's chest and face. It disappeared 24 hours after the paracetamol was discontinued, and reappeared again when the mother was given another 1g dose of paracetamol, 2 weeks later (7).

In a telephone follow-up study, no side effects were noted in 43 breastfed infants whose mothers were taking paracetamol (8). Additionally, no adverse effects were noted in breastfed infants from 2 other studies (4, 9).

Use of combination products

Codeine

Codeine is contra-indicated during breastfeeding and therefore any combination product which also contains codeine should be avoided during the breastfeeding period (10). For further information, see www.sps.nhs.uk/articles/codeine-and-breastfeeding-is-it-safe-and-what-are-the-alternatives/

Caffeine

Combination products containing caffeine should be avoided if possible, especially with a newborn infant. However, if use is unavoidable, then caffeine containing products can be used but monitor the infant for irritability and poor sleep.

Caffeine appears in breastmilk rapidly after maternal consumption. An intake of around 300–500 mg daily might be a safe level of intake for most mothers. At higher levels, irritability and poor sleep may occur in the infant (11, 12). However, newborn infants, and infants up to the age of around 5 months, should be exposed to lower amounts of caffeine via breast milk, because clearance in this group is much slower, and therefore the risk of side-effects is greater (11). Combination products should preferably be avoided in these infants where possible.

It is important to recognise the cumulative contribution that beverages throughout the day (such as tea, coffee, and cola) may make to the overall caffeine intake.

Diphenhydramine

Combination products containing diphenhydramine should be avoided if possible, especially with a newborn infant whilst the breastfeeding process is being established. However, if use is unavoidable, then diphenhydramine containing products can be used but monitor the infant for feeding difficulties and drowsiness.

There are no studies measuring how much diphenhydramine may be present in breast milk, but based on the properties of the drug, this is likely to be very low. Drowsiness has been reported in one infant exposed (11). There is also a theoretical concern that larger doses of diphenhydramine may affect milk production, although this has not been demonstrated from any studies (12).

Diphenhydramine should therefore ideally be avoided whilst the breastfeeding process is being established. However, it is unlikely that the small doses of diphenhydramine found in combination products would be enough to cause any adverse effects.

Ibuprofen

Ibuprofen can be used during breastfeeding and therefore a combination product containing both paracetamol and ibuprofen can also be used during breastfeeding. Negligible amounts of ibuprofen have been reported in breast milk and no adverse effects have been reported in infants (10).

For further information, see <https://www.sps.nhs.uk/articles/can-breastfeeding-mothers-take-ibuprofen/>. For the latest NHS advice regarding the use of ibuprofen to **manage the symptoms of coronavirus (COVID-19)**, see: <https://www.nhs.uk/medicines/ibuprofen-for-adults/>

Phenylephrine

Combination products containing phenylephrine should be avoided if possible, especially with a newborn infant whilst the breastfeeding process is being established. However, if use is unavoidable, then phenylephrine containing products can be used but monitor the infant for feeding difficulties, irritability, and poor sleep.

There are no studies measuring how much phenylephrine may be present in breast milk, but based on the properties of the drug, this is likely to be very low. There is a theoretical concern that larger doses of phenylephrine may affect milk production, although this has not been demonstrated from any studies (12). Phenylephrine should therefore ideally be avoided whilst the breastfeeding process is being established (11). However, it is unlikely that the small doses of phenylephrine found in combination products would be enough to cause any adverse effects.

Pseudoephedrine

Combination products containing pseudoephedrine should be avoided if possible, especially with a newborn infant whilst the breastfeeding process is being established. However, if use is unavoidable, then pseudoephedrine containing products can be used but monitor the infant for irritability, poor sleep, and feeding difficulties.

To date, only small amounts of pseudoephedrine have been found in breast milk, although the evidence to support this is very limited (11). Irritability in breastfed infants has also been reported (11). In addition, there is concern that pseudoephedrine may decrease milk production which may be of particular concern as the breastfeeding process is being established, although evidence has also suggested decreased milk production even in the later stages of breastfeeding (12).

Limitations

Evidence relating to the secretion of paracetamol in breast milk is limited and relatively old. It is based on small population, uncontrolled, single-dose studies. Methodologies for measuring paracetamol levels in breast milk have been varied, although results have shown uniformly low breast milk levels. 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.

The above information applies to maternal monotherapy and a full-term, fit and healthy infant only. Should the infant be premature, unwell, or the mother taking multiple medications, an individual risk assessment is required. Please contact the UK Drugs in Lactation Advisory Service for advice on 0116 258 6491/0121 424 7298 or ukdilas.enquiries@nhs.net.

References

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- US National Library of Medicine Drugs & Lactation (Lactmed) database. Accessed via <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT>
- Medications & Mother's Milk Online. Accessed via <http://www.medsmilk.com/>
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