All correspondence to:
The Breastfeeding Network
PO Box 11126, Paisley PA2 8YB
Admin Tel: 0844 412 0995
e-mail: druginformation@breastfeedingnetwork.org.uk
www.breastfeedingnetwork.org.uk

Introduction to the Safety of Drugs passing through Breastmilk

The information provided is taken from various reference sources. It is provided as a guideline. No responsibility can be taken by the author or the Breastfeeding Network for the way in which the information is used. Clinical decisions remain the responsibility of medical and breastfeeding practitioners. The data presented here is intended to provide some immediate information but cannot replace input from professionals.

Taking medication does not usually mean that a mother has to stop breastfeeding temporarily or permanently. The advantages of breastmilk should never be underestimated nor should the wishes of a mother to continue to breastfeed and the right of the infant to continue to receive it.

The number of adverse reactions to drugs passing through breastmilk is small (Anderson 2003). Warnings about not using a drug in lactation may sometimes be based on one reported incidence.

In general less than 1% of a drug will pass through breastmilk to the baby. Technology exists to measure very small amounts of drugs in milk and plasma. Their detection does not necessarily imply that they will cause harm.

Drug manufacturers are not required to produce clinical data on the safety of the use of a new drug in lactation when applying for a licence to market their product. It is obviously unethical to expose an infant to potential harm. Patient information leaflets provided within drug packs may say "do not take if you are breastfeeding" or "please consult your GP or pharmacist before taking this drug if you are breastfeeding". See information sheet on Patient Information Leaflets on the website www.breastfeedingnetwork.org.uk.

The majority of drugs are unlicensed for use during lactation. This means that the manufacturers have not undertaken research to confirm safety on ethical grounds. Data may be available on the amount which gets into breastmilk. However the person recommending the drug e.g. GP has to take ultimate responsibility for prescribing should there be any adverse effects in the baby.

Current readily available reference books do not provide quantitative data on which to base decisions on whether a drug is safe to be given to a breastfeeding mother. However this data is available.

Before prescribing for any mother and baby pair several factors should be taken into consideration:

- The need of the mother for treatment and any particular drug
- The age and maturity of the baby - liver and kidney systems do not work fully for some time after birth. Premature babies are particularly susceptible to drugs and may exhibit higher than expected drug levels.
- The volume of breastmilk being taken daily – a fully fed two-week-old baby consumes more milk than a nine-month-old feeding just once or twice a day.
- Information available on the safety of the drug.

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Drugs which are safer to prescribe for a breastfeeding mother are:

- Drugs which are highly protein bound so that less drug is free to enter milk
- Drugs which have a low plasma:milk ratio - the lower the ratio the less drug reaches breastmilk. Ratios above 1 imply concentration of the drug in breastmilk
- Those with a shorter half life are preferable as there is less likelihood of the drug building up
- Drugs in which there is experience of use in breastfeeding and published reports. Mothers should be made aware of potential side effects e.g. diarrhoea and/or colic with antibiotics, drowsiness with sedatives and when these are significant and justify stopping the drug, rather than breastfeeding unless the circumstances are exceptional.
- If a drug is available in a formulation for children it is likely to be safe to be taken by breastfeeding women.

It is important that no baby is exposed to risk by the mother taking a drug which is contra-indicated in breastfeeding. It is also important that the baby is not denied the value of continued breastfeeding. Prescribing during lactation is not simple or straightforward and includes dilemmas for mothers and health professionals faced with the lack of good data on which to make decisions. As the number of women who initiate and sustain breastfeeding increases this will become a more important area.

The National Service Framework for Children, Young People and Maternity, 2005 (10.5) stated that:

- mothers who are taking medicines need particular advice about breastfeeding;
- current sources available to healthcare professionals may lead to women, unnecessarily, being advised not to breastfeed;
- women who are taking medicines should receive specialist advice, based on best available evidence, in relation to breastfeeding.

This is reiterated in the National Institute for Health and Clinical Excellence (NICE) Maternal and Child Nutrition Guides (2008) where it is also highlighted that:

- health professionals should discuss the benefits and risks associated with the prescribed medication and encourage the mother to continue breastfeeding, if reasonable to do so. In most cases, it should be possible to identify a suitable medication which is safe to take during breastfeeding by analysing pharmacokinetic and study data. Appendix 5 of the 'British National Formulary' should only be used as a guide as it does not contain quantitative data on which to base individual decisions; and
- health professionals should recognise that there may be adverse health consequences for both mother and baby if the mother does not breastfeed. They should also recognise that it may not be easy for the mother to stop breastfeeding abruptly – and that it is difficult to reverse.

The provision of information to mothers and healthcare professionals on the relative risks of medication taken by breastfeeding mothers is the aim of the Breastfeeding Network, Drugs in Breastmilk Helpline.

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