

**Western Australian
Drugs in Human Milk
Research Group**

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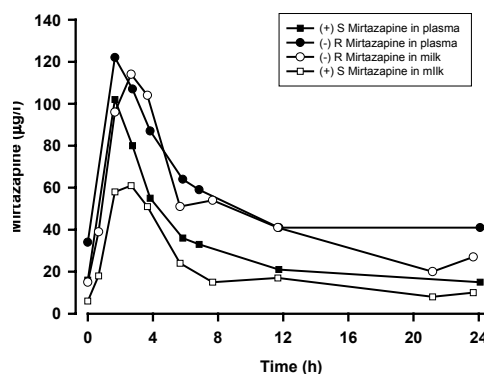
Newsletter #2 - December 2002

Latest data:

In this newsletter we are highlighting a case study of the excretion of the antidepressant **mirtazapine** (Avanza,[®] Remeron[®]) in breastmilk. Mirtazapine is formulated as an equal mixture of the (+) R- and (-) S-enantiomers, and both were measured separately in milk & plasma by high performance liquid chromatography:

Mirtazapine - Patient 1

Case . 32 yr-old Mum taking 45 mg mirtazapine daily (536 µg/kg/day). The average mirtazapine concentrations in milk collected over a dose interval at steady-state was 46.4 µg/L for the (+) R-mirtazapine and 20.3 µg/L for the (-) S-mirtazapine. This translates to an absolute infant dose of 7 µg/kg/day for (+) R-mirtazapine and 3 µg/kg/day for (-) S-mirtazapine. For the two enantiomers combined, and expressed relative to the mothers' dose, the 'relative infant dose' is calculated to be 1.9%.



Interpretation: Generally, a 'relative infant dose' of less than 10% is considered acceptable. In this case the breastfed infant (F, 2 months old) was achieving the expected milestones, had a normal Denver Developmental score (113%), and mirtazapine was not detected in her blood. Hence the 1.9% infant dose was considered safe. Nevertheless, until we accumulate more cases, each needs to be assessed as an individual risk-benefit analysis

Current research studies:

At present we are accumulating data of the following drugs:

dexamphetamine, lamotrigine (Lamictal[®]), mirtazapine (Remeron[®], Avanza[®]), quetiapine (Seroquel[®]), risperidone (Risperdal[®]), and topiramate (Topamax[®]).

If you know of any lactating mothers who are taking these drugs and would be interested in assisting our ongoing research program, please contact Judy Kristensen or Patrick Yapp at the Obstetric Drug Information Service, Women's and Children's Health Service on 08-9340-2722 or Ken Ilett at the UWA on email kilett@receptor.pharm.uwa.edu.au

Recent publications:

1. Ilett KF, Kristensen JH, Hackett LP, Paech M, Kohan R, Rampono J. Distribution of venlafaxine and its O-desmethylmetabolite in human milk and their effects in breastfed infants. *British Journal of Clinical Pharmacology* 2002; **53**: 17-22.
2. Kristensen JH, Hackett LP, Kohan R, Paech M, Ilett KF. The amount of fluvoxamine in milk is unlikely to be a cause of adverse effects in breastfed infants. *Journal of Human Lactation* 2002; **18**:139-142.
3. Hale TW, Ilett KF. *Drug therapy and breastfeeding; from theory to clinical practice*. London: The Parthenon Publishing Group, London, 2002. ISBN 1-84214-110-4.