



Prescribing Information Reminder and Medsafe Alert re Codeine and Tramadol

Prescribing of Controlled Drugs

Midwives are reminded that;

- Midwives **cannot** prescribe Codeine - Misuse of Drugs Act 1975 Schedule Class C2 – controlled drug.
- Under the Medicines Amendment Act 2013 and the Misuse of Drugs Amendment Regulations 2014 (Pursuant to the Misuse of Drugs Act 1975): Midwives may **only** prescribe from the list of controlled drugs in line with Schedule 1C of the Regulations (pethidine, morphine or fentanyl only). Codeine is not part of Schedule 1C.
- The Medicines Amendment Act 2013 requires that before commencing to prescribe the allowed Schedule 1C medicines midwives undertake specific education specified by the responsible regulatory authority.
- The Midwifery Council determines the scope of practice of a midwife in relation to the prescription of opiate analgesia to be for intrapartum use only.
- The College expects midwives prescribing opioids for intrapartum care to be fully conversant with the New Zealand College of Midwives Consensus statements 'Prescribing and administration of opioid analgesia in labour' and 'Midwife Prescribing'.

Midwives Prescribing Tramadol:

According to the Medical Officer of Health, Medicines Control it is expected that midwives would not generally write a prescription for high dose tramadol (i.e greater than 200mgs daily) or for extended periods.

In addition to this advice Medsafe published an Alert Communication (July 2017) on the use of tramadol during breastfeeding. The alert communication can be accessed on the Medsafe website:

www.medsafe.govt.nz/safety/EWS/2017/UseOfTramadolDuringBreastfeeding.asp

The New Zealand College of Midwives offers the following advice:

Small amounts of tramadol are found in breast milk and the effect this has on infants and newborns is not fully known. Therefore, the tramadol data sheets state that breastfeeding while taking tramadol is not recommended. However this advice needs to be considered in relation to the woman's requirement for pain management and the fact that most women take tramadol for a short period of time post natally. The baby's exposure is low when tramadol is taken for a short duration. Prior to lactogenesis 2 the baby's exposure to tramadol would be minimal due to the normal low volumes of colostrum. For babies exposed over a longer period of time the following advice will be helpful.

The following are excerpts from the Medsafe Safety Information Trans-Tasman Early Warning System Alert Communication:

Use of tramadol and codeine during breastfeeding

Information for healthcare professionals

- The benefits and risks of harm of treatment with tramadol in both the mother and baby should be considered as well as the benefits and risks of harm of not treating.
- It is also important to consider the benefits and risks of harm of using an alternative analgesic. Non-steroidal anti-inflammatory drugs (NSAIDs) may not be suitable for some women. Women who are ultra-rapid metabolisers of codeine may have higher morphine levels in their breast milk, which may lead to life-threatening or fatal side effects in newborns. Oxycodone may cause respiratory depression in newborns. Consult the data sheets for more information.
- Discuss with the woman the benefits and risks of harm of using tramadol during breastfeeding.
- The exposure of the baby to tramadol is low at around 112 microgram/kg/day (2.24% relative to the mother) and around 30 microgram/kg/day (0.64% relative to the mother) for the active metabolite when the mother is taking tramadol 100 mg orally every six hours.
- Exposure is likely to be greater the longer the mother takes tramadol since bioavailability increases over time. Advise parents and caregivers to watch closely for signs of breathing problems in infants and newborns exposed to tramadol through breast milk. These signs include slow or shallow breathing, difficulty or noisy breathing, more than usual sleepiness, trouble breastfeeding or limpness.

The following websites may be helpful for midwives to explore further the mechanisms of drug uptake in human milk and identify the current knowledge on the effects of particular medicines in breast milk and on newborns.

<http://www.medsmilk.com/pages/reading>

<http://www.infantrisk.com/>

<http://www.infantrisk.com/content/drug-entry-human-milk>