NZF is changing the way that pregnancy and breast-feeding advice for medicines is presented

From 1 October, 2018, the New Zealand Formulary (NZF) will replace the current pregnancy and breast-feeding advice, which is based on a five-letter classification system, with more comprehensive information from *Drugs in Pregnancy and Lactation*. This move is in line with international recommendations.

Why change pregnancy and breast-feeding advice?

For many decades pregnancy categories have been used to indicate the safety of prescribing medicines to pregnant or breast-feeding women. The New Zealand Formulary used a pregnancy category system from the Therapeutic Goods Administration (TGA) Australia, based on A, B, C, D or X classifications, and breast-feeding information from the Therapeutic Guidelines Limited (TGL), Australia.[1, 2]

The system of using pregnancy categories has several limitations, including that:[1, 3]

- It does not provide information about risks across different trimesters of pregnancy
- Medicines with a wide range of associated risks could be included in the same category
- The categories imply a grading system, which could lead to prescribing based on the risk category rather than an understanding of the evidence of risks and benefits for a particular patient
- The single-letter classification system does not provide enough information to support informed decision making by prescribers and patients

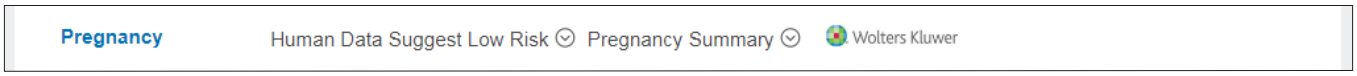
As a result of these limitations, there is an international movement away from using pregnancy safety categories, and instead providing descriptions of the underlying evidence, degree of severity, timing of effects on the developing fetus and also indicating areas where there is a lack of evidence.

New pregnancy and breast-feeding advice

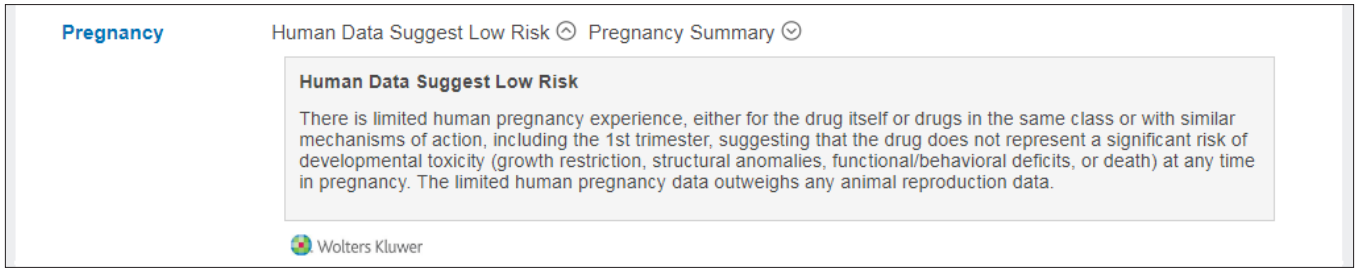
From 1 October, 2018, the NZF will include advice on the safety of medicines in pregnancy and breast-feeding from *Drugs in Pregnancy and Lactation* (used by permission from Wolters Kluwer Health).[4] This information will be available in an expandable section in a medicine monograph.

For example, the current information regarding the safety of prescribing metronidazole in women who are pregnant is classified as "B2":

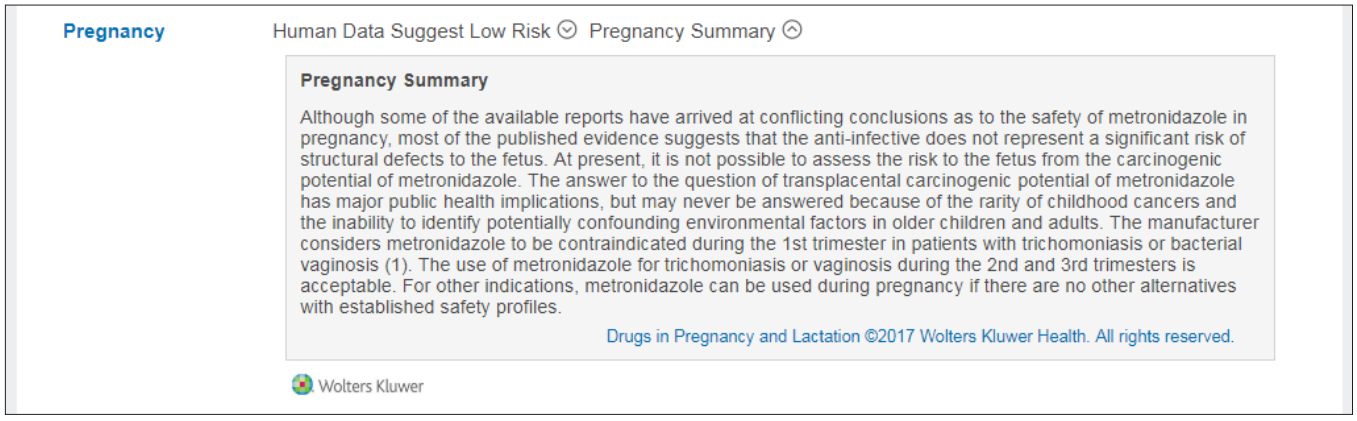
From 1 October, 2018, the pregnancy information for systemic use of metronidazole will show two headers: "Human Data Suggest Low Risk" and "Pregnancy Summary":



Clicking on the arrow icon to the right of "Human Data Suggest Low Risk" will open a description of this risk category:

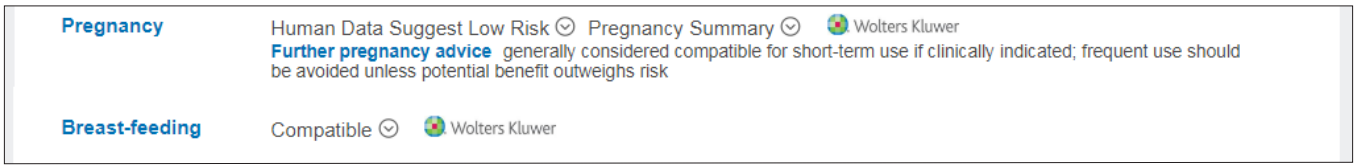


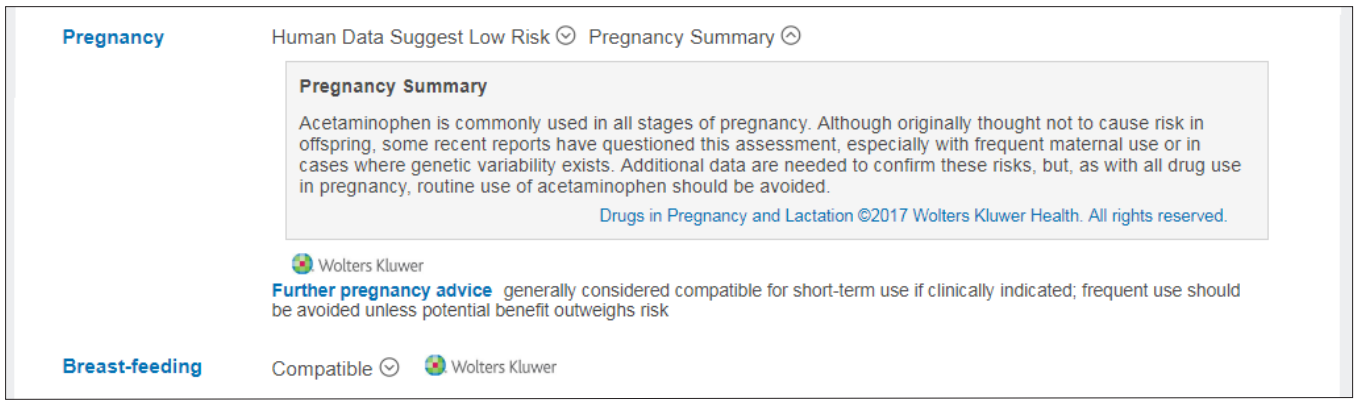
Clicking on the arrow icon to the right of "Pregnancy Summary" will open a brief overview of the evidence regarding the safety of using metronidazole during pregnancy, including available information on risks during different trimesters:

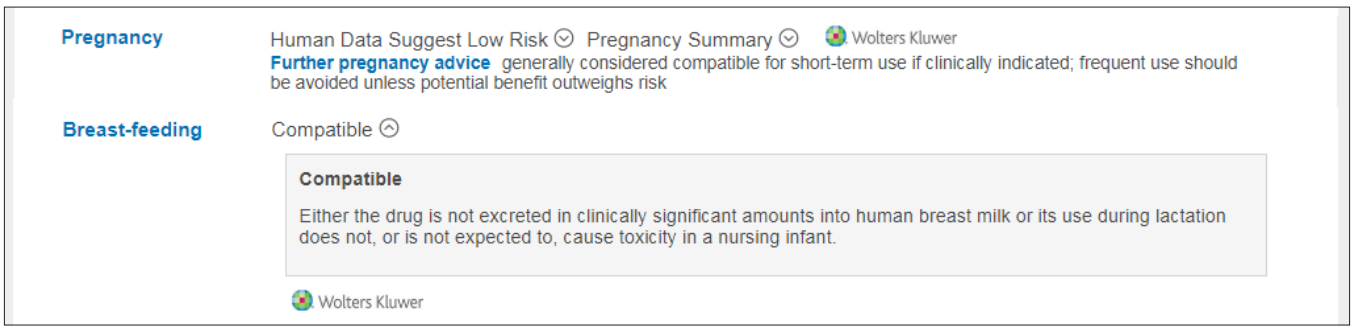


As another example, the current information regarding the safety of prescribing paracetamol in women who are pregnant or breast-feeding is "A"; not known to be harmful, with a compatible rating for breast-feeding:

From 1 October, 2018, the updated pregnancy information will show "Human Data Suggest Low Risk" and "Pregnancy Summary" and the breast-feeding information will show "Compatible". Clicking on the arrow icons next to any of these headings will reveal further information:





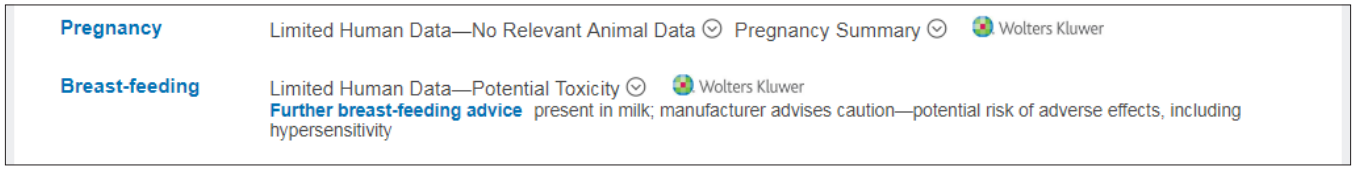


The NZF or NZFC may provide additional advice

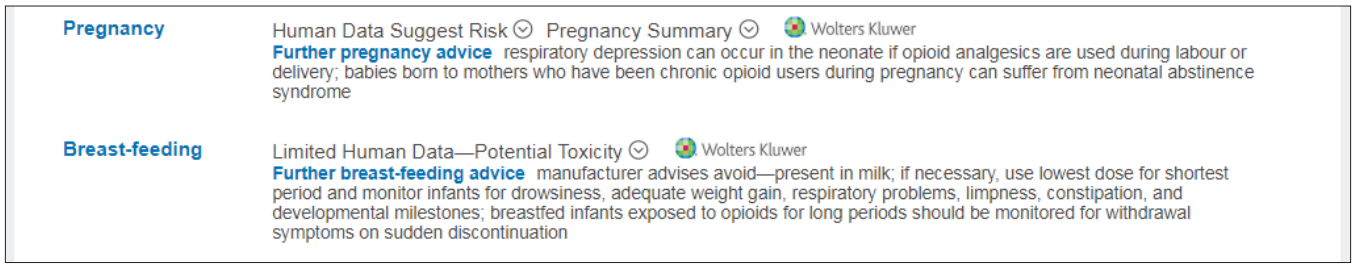
For some medicines additional information will be included with a "Further pregnancy advice" or "Further breast-feeding advice" header.

For example, the prescribing recommendations on the use of morphine or allopurinol during breast-feeding will show "Limited Human Data – Potential Toxicity" with additional advice below under the "Further breast-feeding advice" headers:

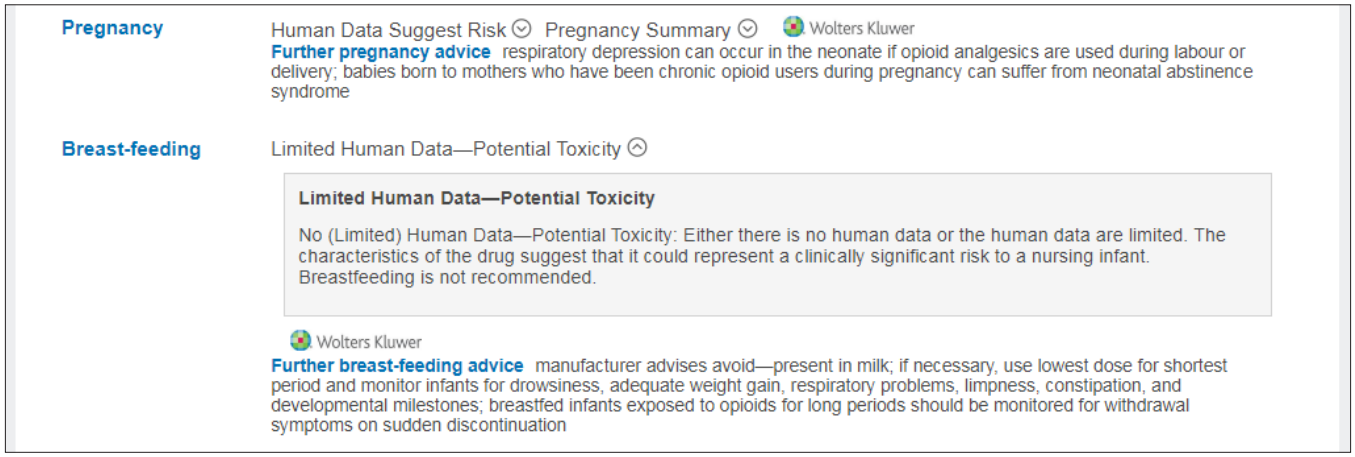
Advice for allopurinol use in women who are breast-feeding:



Advice for morphine use in women who are breast-feeding:



Clicking on the "Limited Human Data – Potential Toxicity" header will open a description of this risk category:



Alternative advice will be included if medicine information is not available

For some medicines the NZF or NZFC will provide alternative advice if information regarding its safety in pregnancy or breast-feeding is not available in *Drugs in Pregnancy and Lactation*.

From 1 October, 2018, contraception advice will be included under a separate header

Medicine monographs will now also include a "Contraception and conception" section, which will contain information about any precautionary measures for women or men of childbearing age due to potential teratogenicity, including:

- Recommendations on the type of contraception
- Potential interactions with contraceptives
- Duration of continuing with contraception after a medicine has been stopped

References:

1. Temming LA, Cahill AG, Riley LE. Clinical management of medications in pregnancy and lactation. Am J Obstet Gynecol 2016;214:698–702. doi:10.1016/j.ajog.2016.01.187
2. Therapeutic Goods Administration (TGA). Australian categorisation system for prescribing medicines in pregnancy. Therapeutic Goods Administration (TGA) 2011. Available from: https://www.tga.gov.au/australian-categorisation-system-prescribing-medicines-pregnancy (Accessed Aug, 2018).
3. Mosley JF, Smith LL, Dezan MD. An overview of upcoming changes in pregnancy and lactation labeling information. Pharm Pract (Granada) 2015;13:605.
4. Briggs G, Freeman R, Towers C, et al. Drugs in pregnancy and lactation. 11th edition. Wolters Kluwer 2017. Available from: www.lww.co.uk/drugs-in-pregnancy-and-lactation-11e (Accessed Aug, 2018).