## UKDILAS - Website Changes Alert

uk Medicines Information



**Date: 1st July 2017**

**Issue No: 1**

**UKDILAS – Website Changes Alert** aims to inform Trent and West Midlands Medicines Information Centres of changes that have been made to the SPS website and other linked UKDILAS sources. These summaries are available [through this link](http://www.midlandsmedicines.nhs.uk/content.asp?section=6&subsection=17&pageIdx=7). Feedback on this Alert is welcomed.

**CHANGES**

The list below details the changes in recommendations and supporting information resulting from new published evidence or guidance relating to drugs used during lactation. Major changes will be indicated with **✯.** The source for the change will normally be through routine assessment of newly published evidence (A) or through the ongoing process of UKDILAS database revision (B).

| **Drug** | **Change from** | **Change to** | **Reason for change** | **Source** |
| --- | --- | --- | --- | --- |
| **Aspirin (low dose)** | Single case reports in breastfed infants of metabolic acidosis (after prolonged, high dose) and symptoms of delayed thrombocytopenic purpura.  Low doses (75mg daily) considered to present a low risk but avoid in infants with a viral infection or fever | Very limited published evidence of safety for low-dose aspirin and no adverse effects reported with low dose aspirin in breastfed infants  Low doses (up to 81mg daily) considered to present a low risk but avoid in infants with a viral infection or fever | New quantitative report of 7 mothers taking 81mg/d.  Risk of adverse effects occurring with low-dose aspirin, as observed with high dose aspirin, re-assessed. | A1 |
| **Cabergoline** | - | **Summary** - Deleted sentence ‘Cabergoline has not been associated with serious maternal adverse effects’. | New case report (abstract only). Mother experienced a number of severe symptoms after a single dose for lactation suppression. | A2 |
| **Certolizumab pegol** | Very limited published evidence of safety indicates small amounts in breast milk | Moderate level of evidence of use in breastfeeding indicates small amounts in breast milk. | New quantitative study of 17 mothers.  All published reports include 23 mothers in 4 studies. | A3 |
| **Dexmedetomidine** | No published evidence of safety. | Very limited published evidence of safety  Small amounts in breast milk | New quantitative study in 4 women showing low milk levels, undetectable at 24h. | A4 |
| **Iron isomaltoside** | No published evidence of safety | Very limited published evidence of safety | New quantitative study of 30 mothers. | A5 |
| **Lacosamide** | No published evidence of safety. | Very limited published evidence of safety | 2 new studies. One quantitative case report and one observational study with 3 infants showing no long-term effects. | A6,7 |
| **Rituximab**  ***(lymphoma/CLL)*** | Low levels anticipated in milk due to the drug’s properties | Very limited published evidence of safety  Small amounts in breast milk | New quantitative case report showing very low milk levels.  Also, entries for lymphoma/CLL and rheumatoid arthritis made consistent. | A8 |
| **Rituximab**  ***(rheumatoid arthritis)*** | No published evidence of safety  Low levels anticipated in milk due to the drug’s properties and likely to be degraded in infant’s GI tract | Very limited published evidence of safety  Small amounts in breast milk |
| **Teicoplanin** | No published evidence of safety | Only very limited anecdotal evidence of safety which indicates no effects in a breastfed infant | New observational case - no adverse effects observed in infant. | A9 |
| **Tramadol** | - | [ADD] FDA advise against tramadol use with breastfeeding in USA on theoretical grounds. However, no adverse effects reported in breastfed infants | FDA advise that tramadol is treated the same as codeine and not used in breastfeeding mothers as it also has a CYP2D6 dependence, although no adverse effects reported in breastfed infants. Advice not yet mirrored by EMA/MHRA. | A10 |

1. Datta P et al. Transfer of low dose aspirin into human milk. J Hum Lact 2017;33:296–9.
2. Chouchana L et al. Neurovascular adverse effects following cabergoline administration in puerperal period. Fundam Clin Pharmacol 2016;30 (Suppl 1):27-8. Abstract PM1-013.
3. Clowse ME et al. Evaluating transfer of certolizumab pegol into breast milk: Results from a prospective, postmarketing, multicenter pharmacokinetic study. Arthritis Rheumatol 2016;68 (Suppl S10):2636-9.
4. Nakanishi R et al. Detection of dexmedetomidine in human breast milk using liquid chromatography-tandem mass spectrometry: Application to a study of drug safety in breastfeeding after Cesarean section. J Chromatogr B Analyt Technol Biomed Life Sci 2017;1040:208-13.
5. Holm C et al. Iron concentration in breast milk normalised within one week of a single high-dose infusion of iron in randomised controlled trial. Acta Paediatr 2017;106:256–60.
6. AZarubova J et al. Plasma and breast milk levels of lacosamide before, during and post pregnancy. Epilepsia 2016;57 (Suppl S2):69. Abstract P193.
7. Lattanzi S et al. Lacosamide during pregnancy and breastfeeding. Neurol Neurochir Pol 2017;51:266-9.
8. Bragnes Y et al. Low level of rituximab in human breast milk in a patient treated during lactation. Rheumatology (Oxford) 2017; Feb 27. [Epub ahead of print].
9. Kaplan YC et al. Teicoplanin use during breastfeeding. Breastfeed Med 2017;12:124.
10. US Food & Drugs Administration. FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. Drug Safety Communication 2017; 4-20-2017

**NEW DRUGS**

No new drugs have been added to the UKDILAS database in the last month.

**PLANNED REVISIONS**

The entries for all drugs in the UKDILAS database are reviewed systematically every three years as part of a rolling programme. As a result three sections of the BNF – Gastrointestinal, Cardiovascular, and Respiratory – have been re-assessed and appropriate changes made to entries on the SPS website and other UKDILAS resources. This ongoing process is supplementary to changes made as a result of new evidence (see section 1).

As groups of drugs are reviewed and changes made to the SPS website notification will be made in this section.