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OFFICIAL RESPONSE STATEMENT **September 2019**

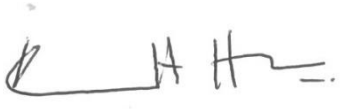
EMA Pharmacovigilance Risk Assessment Committee (PRAC), Recommendations on signals adopted at the 8-11th July meeting. Ondansetron; Signal of birth defects following in-utero exposure during the first trimester of pregnancy arising from recent publications

UKTIS, in collaboration with the European Network of Teratology Information Services (ENTIS), have issued a joint statement (see below) in response to the recommendations from the EMA PRAC regarding the use of ondansetron in the first trimester of pregnancy [1].

In summary:

- The background risk for orofacial cleft is 11 per 10,000 pregnancies
- The risk of orofacial cleft is 14 per 10,000 pregnancies following ondansetron use in the first trimester [2]
- This equates to an additional 3 cases of orofacial cleft per 10,000 pregnancies exposed to ondansetron
- UKTIS recommend that ondansetron should be reserved as a **second line** agent for the treatment of nausea and vomiting in pregnancy (as currently recommended by the RCOG Green-top Guideline) [3].
- Patients must be adequately counselled regarding the benefits of ondansetron together with the small increase in risk of orofacial cleft which **may** exist.
- Ondansetron should still be considered an option for patients with severe vomiting in pregnancy in whom first line treatments have failed.

For more information please see our recently updated monograph 'Use of Ondansetron in Pregnancy' (available from www.toxbase.org or in summary format at www.medicinesinpregnancy.org/bumps/monographs/use-of-ondansetron-in-pregnancy/). Patient information is also available through BUMPS (www.medicinesinpregnancy.org). Health professionals can discuss patient specific enquiries through the UKTIS telephone information line (0344 892 0909, available Monday to Friday 9am to 5pm).



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