



**TITLE:** Aripiprazole for Pregnant Women: Safety

**DATE:** 4 November 2014

## RESEARCH QUESTION

What is the clinical evidence regarding the safety and harms of aripiprazole in pregnant women?

## KEY FINDINGS

One non-randomized study was identified regarding the safety and harms of aripiprazole in pregnant women.

## METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 10), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2009 and October 24, 2014. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

## SELECTION CRITERIA

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

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**Table 1: Selection Criteria**

<b>Population</b>	Pregnant women with mental disorders
<b>Intervention</b>	Aripiprazole (Abilify)
<b>Comparator</b>	No comparator
<b>Outcomes</b>	Clinical harm (fetus development)
<b>Study Designs</b>	Health technology assessments, systematic reviews, meta-analyses, non-randomized studies

## RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by non-randomized studies.

One non-randomized study was identified regarding the safety and harms of aripiprazole in pregnant women. No relevant health technology assessments, systematic reviews, or meta-analyses were identified.

Additional references of potential interest are provided in the appendix.

## OVERALL SUMMARY OF FINDINGS

In one non-randomized study<sup>1</sup> women who received new atypical anti-depressants and anti-psychotics (including aripiprazole) during pregnancy were compared with women who received non-teratogenic drugs during pregnancy and pregnancies in the general population. The authors observed a higher occurrence of abortions and prematurity in the group of women who took atypical anti-psychotics.

## REFERENCES SUMMARIZED

### Health Technology Assessments

No literature identified.

### Systematic Reviews and Meta-analyses

No literature identified.

### Non-Randomized Studies

1. Manakova E, Hubickova L. Antidepressant drug exposure during pregnancy. CZTIS small prospective study. Neuro Endocrinol Lett. 2011;32 Suppl 1:53-6.  
[PubMed: PM22167208](#)

### PREPARED BY:

Canadian Agency for Drugs and Technologies in Health

Tel: 1-866-898-8439

[www.cadth.ca](http://www.cadth.ca)



## APPENDIX – FURTHER INFORMATION:

### Systematic Reviews – Aripiprazole not Mentioned in Abstract

2. Gentile S. Antipsychotic therapy during early and late pregnancy. A systematic review. *Schizophr Bull* [Internet]. 2010 May [cited 4 Nov 2014];36(3):518-44. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2879689>  
[PubMed: PM18787227](#)

### Non-Randomized Studies – Aripiprazole not Mentioned in Abstract

3. Sadowski A, Todorow M, Yazdani BP, Koren G, Nulman I. Pregnancy outcomes following maternal exposure to second-generation antipsychotics given with other psychotropic drugs: a cohort study. *BMJ Open* [Internet]. 2013 [cited 4 Nov 2014];3(7). Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3710985>  
[PubMed: PM23852139](#)
4. Habermann F, Fritzsche J, Fuhrbruck F, Wacker E, Allignol A, Weber-Schoendorfer C, et al. Atypical antipsychotic drugs and pregnancy outcome: a prospective, cohort study. *J Clin Psychopharmacol*. 2013 Aug;33(4):453-62.  
[PubMed: PM23764684](#)
5. Peng M, Gao K, Ding Y, Ou J, Calabrese JR, Wu R, et al. Effects of prenatal exposure to atypical antipsychotics on postnatal development and growth of infants: a case-controlled, prospective study. *Psychopharmacology (Berl)*. 2013 Aug;228(4):577-84.  
[PubMed: PM23559219](#)
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[PubMed: PM22474072](#)
7. Wichman CL. Atypical antipsychotic use in pregnancy: a retrospective review. *Arch Womens Ment Health*. 2009 Feb;12(1):53-7.  
[PubMed: PM19137446](#)

### Clinical Guidelines

8. Katzman MA, Bleau P, Blier P, Chokka P, Kjemisted K, Van Ameringen M, et al. Canadian clinical practice guidelines for the management of anxiety, posttraumatic stress and obsessive-compulsive disorders. *BMC Psychiatry* [Internet]. 2014 [cited 4 Nov 2014]; 14(Suppl 1):S1. Available from: <http://www.biomedcentral.com/content/pdf/1471-244X-14-S1-S1.pdf>  
See: *Atypical Antipsychotics*, page 39
9. Galbally M, Snellen M, Walker S, Permezel M. Management of antipsychotic and mood stabilizer medication in pregnancy: recommendations for antenatal care. *Aust N Z J Psychiatry*. 2010 Feb;44(2):99-108.  
[PubMed: PM20113298](#)

10. de Leon J, Greenlee B, Barber J, Sabaawi M, Singh NN. Practical guidelines for the use of new generation antipsychotic drugs (except clozapine) in adult individuals with intellectual disabilities. *Res Dev Disabil.* 2009 Jul;30(4):613-69.  
[PubMed: PM19084370](#)

### Review Articles

11. Gentile S. A safety evaluation of aripiprazole for treating schizophrenia during pregnancy and puerperium. *Expert Opin Drug Saf.* 2014 Aug 19;1-10.  
[PubMed: PM25139223](#)
12. Galbally M, Snellen M, Power J. Antipsychotic drugs in pregnancy: a review of their maternal and fetal effects. *Ther Adv Drug Saf.* [Internet] 2014 Apr [cited 4 Nov 2014]; 5(2):100-9. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110873>  
[PubMed: PM25083265](#)
13. Windhager E, Kim SW, Saria A, Zauner K, Amminger PG, Klier CM. Perinatal use of aripiprazole: plasma levels, placental transfer, and child outcome in 3 new cases. *J Clin Psychopharmacol.* 2014 Oct;34(5):637-41.  
[PubMed: PM24949701](#)
14. Robakis T, Williams KE. Atypical antipsychotics during pregnancy. *Current Psychiatry* [Internet]. 2013 July [cited 4 Nov 2014]; 12(7): 12-18. Available from: [http://www.currentpsychiatry.com/index.php?id=31597&type=98&tx\\_ttnews\[tt\\_news\]=213016&cHash=da03e20e36](http://www.currentpsychiatry.com/index.php?id=31597&type=98&tx_ttnews[tt_news]=213016&cHash=da03e20e36)
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[PubMed: PM22848828](#)
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[PubMed: PM20465753](#)
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[PubMed: PM19461391](#)

### Additional References

19. Guillen JM, Company ES. Use of antipsychotics during pregnancy and breastfeeding. *Rev Psiquiatr Salud Mental.* 2009 Jul;2(3):138-45.  
[PubMed: PM23034313](#)