

# Pregnancy and neonatal outcome following agomelatine and pipamperone exposure during pregnancy: a case series from the Netherlands

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## Background

Antidepressants and antipsychotics are regularly used in pregnancy, although available safety data vary across substances. For the **antidepressant ‘agomelatine’ and the antipsychotic drug ‘pipamperone’, no pregnancy cases** have yet been published in the literature.

## Objective

This study aimed to provide evidence on the safety of ‘agomelatine’ and ‘pipamperone’ use during pregnancy.

## Methods

The prospective **pregnancy registries of TIS Lareb were screened** for cases with outcome data from inception till Feb '21.

## Results

### Agomelatine (N = 2 cases)

- Both women were exposed during the 1<sup>st</sup> trimester (at 50mg/day and unknown dose), along with other psychotropics.
- Pregnancy complications: hyperemesis gravidarum (N=1) and gestational diabetes (N=1), each in one pregnancy.
- **Two live births with neither congenital malformations, prematurity, low birth weight nor abnormal Apgar at 5’.**
- **One neonatal complication** was reported, but no specific details were available.

### Pipamperone (N = 15 cases)

- Eight women were exposed only during the 1<sup>st</sup> trimester and three during each pregnancy trimester (20-80mg/day).
- Pregnancy complications were reported for three pregnancies: 1) an intra-uterine infection and premature rupture of membranes; 2) pre-eclampsia; and 3) abnormal maternal weight gain (in a woman with pre-existent diabetes).
- **13 live births and 2 ETOPs** (one due to unplanned pregnancy, one unknown reason).
- **No congenital malformations** were observed; one infant had a short neck but no chromosomal abnormalities.
- **Prematurity occurred in three pregnancies** (at 30, 33 and 34 weeks).
- The single neonate with a birth weight of <2500gram (i.e., 969 grams) was born at 30 weeks from a mother with preeclampsia who had smoked 12-30 cigarettes/day.
- **Apgar scores after 5 min were normal** for all neonates.
- **Neonatal complications** were reported for **4/13 neonates**: 1) circulation problems, hyperbilirubinemia and anemia (in the neonate born at 30 weeks); 2) oxygen deficiency due to prolonged labor; and 3-4) unknown.

## Discussion and conclusions

- This case series presents the **first data following agomelatine and pipamperone exposure during pregnancy.**
- Due to a lack of available evidence, **more investigations are needed** to allow a correct benefit/risk assessment of these medicines in the future.

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