

# **Antipsychotics (conventional and atypical) and use during the third trimester of pregnancy and risk of abnormal muscle movements and/or withdrawal symptoms in newborns**

**Final SmPC and PL wording agreed by PhVWP in September 2011**

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## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **Section 4.6 Fertility, pregnancy and lactation**

Neonates exposed to antipsychotics (including [NAME]) during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, or feeding disorder. Consequently, newborns should be monitored carefully.

### **Section 4.8 Undesirable effects**

System Organ Class: Pregnancy, puerperium and perinatal conditions.  
Adverse Drug Reaction / Frequency: Drug withdrawal syndrome neonatal (see 4.6) / not known.

## **PATIENT INFORMATION LEAFLET**

### **Pregnancy and breast-feeding**

The following symptoms may occur in newborn babies, of mothers that have used [NAME] in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.