

SSRIs, venlafaxine and mirtazapine
And the risk of Persistent Pulmonary Hypertension in Neonates (PPHN)
Final SPC and PL wording agreed by the PhVWP in March 2010

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SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.6 for all SSRIs

Epidemiological data have suggested that the use of SSRIs in pregnancy, particular in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN). The observed risk was approximately 5 cases per 1000 pregnancies. In the general population 1 to 2 cases of PPHN per 1000 pregnancies occur.

Section 4.6 for venlafaxine

Epidemiological data have suggested that the use of SSRIs in pregnancy, particularly in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN). Although no studies have investigated an association of PPHN to SNRI treatment, this potential risk cannot be ruled out with <TRADENAME/SUBSTANCE> taking into account the related mechanism of action (inhibition of the re-uptake of serotonin).

Section 4.6 for mirtazapine

Epidemiological data have suggested that the use of SSRIs in pregnancy, particularly in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN). Although no studies have investigated the association of PPHN to mirtazapine treatment, this potential risk cannot be ruled out taking into account the related mechanism of action (increase in serotonin concentrations).

PACKAGE LEAFLET

Section 2 for all SSRIs – subsection pregnancy and breast-feeding

Make sure your midwife and/or doctor know you are on <TRADENAME>. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like <TRADENAME> may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

Section 2 for venlafaxine and mirtazapine – subsection pregnancy and breast-feeding

Make sure your midwife and/or doctor knows you are on <TRADENAME>. When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.