

Fluoxetine and the risk of Congenital Malformations

Final SPC and PL wording agreed by the PhVWP in March 2010

Doc. Ref.: CMDh/PhVWP/018/2010

March 2010

SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.6

Some epidemiological studies suggest an increased risk of cardiovascular defects associated with the use of fluoxetine during the first trimester. The mechanism is unknown. Overall the data suggest that the risk of having an infant with a cardiovascular defect following maternal fluoxetine exposure is in the region of 2/100 compared with an expected rate for such defects of approximately 1/100 in the general population.

PACKAGE LEAFLET

Pregnancy, breast-feeding and Prozac.

Talk to your doctor as soon as possible if you're pregnant, if you might be pregnant, or if you're planning to become pregnant.

In babies whose mothers took Prozac during the first few months of pregnancy, there have been some reports showing an increased risk of birth defects, in particular those affecting the heart. In the general population, about 1 in 100 babies are born with a heart defect. This increased to about 2 in 100 babies in mothers who took Prozac. You and your doctor may decide that it is better for you to gradually stop taking Prozac while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Prozac.