7th September 2005

MEDIA RELEASE

CAUTION OVER ANTIDEPRESSANT PAROXETINE DURING PREGNANCY

Australia’s medicines watchdog, the Therapeutic Goods Administration (TGA), has today advised pregnant women who are taking the antidepressant, Paroxetine, to discuss this treatment with their doctor, following some new information from overseas that suggests there may be a slight increased risk to their babies.

Preliminary analysis of data from a large study conducted in the United States suggests that there may be an increased risk of birth defects and cardiovascular malformation in babies whose mothers are taking Paroxetine.

Australia’s Chief Medical Officer, Professor John Horvath, has cautioned pregnant women not to suddenly discontinue using the medicine as the withdrawal symptoms could be harmful.

“It’s important for the small number of women who would be taking this drug not to panic but to review their treatment with their doctor,” Professor Horvath said.

Paroxetine is registered in Australia under the trade names Aropax, Oxetine, Paxtine, Chemmart, GenRx and Terry White Chemists Paroxetine, Paroxetine-RL, Paroxetine-BC, Paroxetine Hexal, Espar, Loxamine, Paroxat CR and Ausrox.

In Australia, Paroxetine is already classified as a Category C medicine in the product information documents for health professionals. This classification is given to medicines that have caused or are suspected of causing harmful effects to the foetus.

While the research results are not final or verified as yet, the TGA and the sponsor of Paroxetine in Australia, GlaxoSmithKline, are now strengthening the warnings on product information to advise against use during pregnancy.

It must also be emphasised that, even though the research signals there may be a low level increase in risk of malformations, these were of a common type that can spontaneously occur and even reverse after birth. In addition, the majority of babies of women taking Paroxetine in this study were born healthy.

More information can be obtained at the GSK Hotline: 1800 010 462
Fact Sheets can be found on www.tga.gov.au

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