PUBLIC ADVISORY
IMPORTANT SAFETY INFORMATION
REGARDING PAXIL® IN PEDIATRIC PATIENTS

GlaxoSmithKline

PAXIL® (paroxetine hydrochloride) should not be given to children and adolescents under 18 years of age due to a possible increased risk of suicide-related adverse events

MISSISSAUGA, Ontario (July 15, 2003) - GlaxoSmithKline Inc., following discussions with Health Canada, is alerting patients, their parents or guardians, and healthcare professionals that until further information is available Paxil should not be given to pediatric patients (children and adolescents under 18 years of age), due to concerns of a possible increased risk of suicidal thinking, suicide attempts or self-harm. Paxil must not be used in pediatric patients with major depressive disorder, due to the additional fact that studies have failed to show that Paxil was effective in this patient population.

Paxil is a drug prescribed by doctors to relieve symptoms of depression and anxiety disorders. These new safety concerns for patients under 18 years of age do not affect the use of Paxil in adults. Paxil is not approved in Canada for use in children and adolescents under 18 years of age.

It is very important that Paxil not be discontinued abruptly. Parents or guardians of pediatric patients or adolescents who are being treated with Paxil should consult with their doctors before discontinuing their medication. A doctor may decide to continue treatment with Paxil if the patient is responding well. Should the decision be made to stop treatment with Paxil, a gradual reduction in the dose under medical supervision is recommended due to the risk of discontinuation symptoms.

There is new evidence from pediatric clinical trials in major depressive disorder of an increased risk of suicidal thinking, suicide attempts or self-harm in patients treated with Paxil, compared to those treated with placebo (sugar pill). Reports of suicidal thinking and self-harm in Paxil-treated patients were also seen in pediatric trials in social anxiety disorder. Overall, the rate of such adverse events was higher in the Paxil-treated pediatric patients compared to placebo-treated patients. There were no suicides in the pediatric clinical trial program, which included more than 1,000 patients treated with the medication.

The study results also did not show that Paxil is effective in treating depression in pediatric patients. In view of this set of findings, and because depression may occur at the same time as anxiety disorders, such as obsessive compulsive disorder or social anxiety disorder, Paxil should not be given to children and adolescents under 18 for any indication, until further information is available.

GlaxoSmithKline has sent a letter to healthcare professionals informing them of the new safety information. This information may be obtained on the Canadian website of GlaxoSmithKline (http://www.gsk.ca) or on the website of the Therapeutic Products Directorate of Health Canada (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_professionals_e.html). The company is working with Health Canada to revise the Canadian prescribing information for Paxil. If patients have questions regarding their current Paxil prescription, they are asked to contact their doctor or pharmacist.

For media inquires, please contact Alison Steeves or Jill McKinlay, (905) 819-3363.

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Any suspected adverse reactions can also be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0201C2
OTTAWA, Ontario, K1A 1B9
Tel: (613) 957-0337 or Fax: (613) 957-0335
Toll free for consumers and health professionals:
Tel: 866 234-2345, Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the TPD web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.