

MESSAGE FROM PROFESSOR G DUFF, CHAIRMAN OF COMMITTEE ON SAFETY OF MEDICINES

10 June 2003

Dear Colleague

SAFETY OF SEROXAT (PAROXETINE) IN CHILDREN AND ADOLESCENTS UNDER 18 YEARS- CONTRAINDICATION IN THE TREATMENT OF DEPRESSIVE ILLNESS

I am writing to inform you about new evidence relating to the efficacy and safety of Seroxat (paroxetine) in children and adolescents under the age of 18 years when used to treat depressive illness. Seroxat is one of a class of anti-depressants, the Selective Serotonin Re-uptake Inhibitors (SSRIs). It is not licensed for use in children but it is used in this age group outside the licensed indications.

New data from clinical trials in children and adolescents were received by the Medicines and Healthcare products Regulatory Agency (MHRA) at the end of May 2003. These new data have been reviewed by an Expert Working Group on SSRIs and the Committee on Safety of Medicines (CSM). These data do not demonstrate efficacy in depressive illness in this age group and show an increase in the risk of harmful outcomes including episodes of self-harm and potentially suicidal behaviour in the Seroxat group compared to placebo. Various analyses suggest that the risk of these outcomes is between 1.5 and 3.2 times greater with Seroxat compared to placebo. On the basis of these data, CSM has advised that the balance of risks and benefits of Seroxat is unfavourable when used to treat depressive illness in this age group. CSM has advised that Seroxat should not be used in children and adolescents under the age of 18 years to treat depressive illness. The efficacy and safety of Seroxat for children in other indications have not been established.

Product information for Seroxat is being updated to include this new advice and the revised Summary of Product Characteristics is available on the Electronic Medicines Compendium website and will be sent to Child and Adolescent Psychiatrists and General Practitioners shortly.

Prescribing advice – children and adolescents with depressive illness:

1. Seroxat should not be prescribed as new therapy for patients under 18 years of age with depressive illness.
2. If your patient is being successfully treated with Seroxat, then the completion of the planned treatment course should be considered as an option in the management of the illness.

3. If your patient is not doing well on Seroxat, change of treatment should be considered.

When stopping treatment with Seroxat:

Seroxat should not be stopped suddenly because of the risk of withdrawal reactions. The dose should be reduced very gradually, using half tablets, and then alternating days, if necessary. If the dose is not tapered, there is a greater chance of experiencing side effects. For the majority of people, symptoms go away on their own within 2 weeks. If side effects are intolerable on dose reduction or stopping, the dose should be increased and subsequently reduced more gradually.

Adults

Paroxetine has been demonstrated to be effective in adults with depressive illness and the CSM advises that the balance of risks and benefits of paroxetine remains positive. However the implications of the new paediatric data on the safety of paroxetine in the adult population remains under close review by the CSM and its Expert Working Group.

Further information on Seroxat for prescribers and patients is available on the website of the Medicines and Health Care Products Regulatory Agency (MHRA). Should you require any additional information, please telephone the MHRA on 0207 273 0000.

Please report any serious suspected adverse reactions to Seroxat (paroxetine) via the Yellow Card reporting scheme to the CSM/ MHRA

Professor Gordon Duff

Chairman – Committee on Safety of Medicines