

From The Chief Medical Officer:
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HSS(MD)38/2003

To: All General Practitioners - please ensure this message is seen by all practice nurses and non-principals working in your practice and retain a copy in your 'locum information pack'.

Directors of Public Health to forward to:

All General Practitioners

Medical Directors of HSS Trusts to forward to:

-Consultant Psychiatrists

-Consultant Paediatricians (Acute and Community)

-Consultant Psychiatrists in Child and Adolescent Mental Health

Directors of Nursing of HSS Boards

Directors of Nursing of HSS Trusts to forward to:

Key teams working in Child and Adolescent Mental Health Nursing and Children's Nursing

Chief Pharmacists of HSS Boards and HSS Trusts

Community Pharmacists

19 September 2003

Dear Colleague

SAFETY OF VENLAFAXINE (EFEXOR, EFEXOR XL) IN CHILDREN AND ADOLESCENTS UNDER 18 YEARS IN THE TREATMENT OF DEPRESSIVE ILLNESS

We wish to alert you to new information from the Committee of Safety of Medicines. The Committee advises that Venlafaxine (Efexor, Efexor XL) should not be used in children and adolescents under the age of 18 years in the treatment of depressive illness.

New results from clinical trials in children and adolescents have been reviewed by the Committee on Safety of Medicines (CSM) Expert Working Group on selective serotonin re-uptake inhibitors (SSRIs). The trials did not demonstrate efficacy in depressive illness in this age group (6-17 years) and showed an increase in the rate of harmful outcomes including hostility, suicidal ideation and self-harm in the venlafaxine (Efexor, Efexor XL) group compared with the placebo group. In the MDD (major depressive disorder) trials, the most common adverse events leading to discontinuation in at least 1% of children and adolescents treated with venlafaxine, and at a rate twice that of placebo, were as follows (percentages listed for venlafaxine and placebo respectively): hostility (2%, <1%) and suicidal ideation (2%, 0%). In addition, there were three suicide attempts in the venlafaxine group, compared with none in the placebo group. There were no suicides. Other adverse events occurring more commonly in the venlafaxine group were abdominal pain, loss of appetite and weight loss.

On the basis of these findings, the CSM's Expert Working Group has advised that the balance of risks and benefits of venlafaxine is unfavourable for the treatment of depressive illness in this age group. The Expert Working Group has advised that venlafaxine should not be used in children and adolescents under the age of 18 years for the treatment of depressive illness. The efficacy and safety of venlafaxine for other indications in children and adolescents under the age of 18 years have not yet been established.

Venlafaxine should not be stopped suddenly because of the risk of withdrawal reactions. The dose should be gradually reduced over at least two weeks and the patient monitored in order to minimise the risk of withdrawal reactions. The period for discontinuation may depend on the dose, duration of therapy and the individual patient. If the dose is not tapered, there is a greater chance of experiencing side effects on withdrawal. Until further advice is issued, treatment of depressive illness in this age group should be as advised by a specialist.

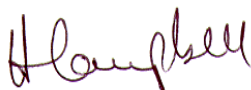
The latest edition of Current Problems in Pharmacovigilance summarises the licensed indications of SSRIs and venlafaxine in children and adolescents.

Further information on venlafaxine for prescribers and patients is available on the website of the Medicines and Healthcare products Regulatory Agency (MHRA) <http://www.mhra.gov.uk>. The company, Wyeth, will be issuing revised product information shortly. Should you require any additional information, please telephone 0207 273 0000 at the MHRA. Please report any suspected adverse reactions to venlafaxine via the Yellow Card reporting scheme to the CSM/MHRA.

This letter is available at www.dhsspsni.gov.uk and also on the DHSSPS Extranet which can be accessed directly at <http://extranet.dhsspsni.gov.uk> or by going through the HPSS Web at <http://www.n-i.nhs.uk> and clicking on DHSSPS.

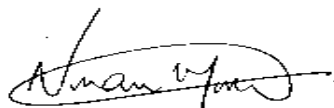
We would wish you to bring this information to the attention of key staff working in this area, as a matter of urgency.

Yours sincerely



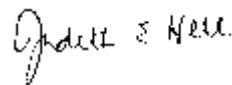
H CAMPBELL (Dr)

Yours sincerely



N MORROW (Dr)

Yours sincerely



J HILL (Miss)

cc Chief Executives of HSS Boards and HSS Trusts