

From the Chief Medical Officer:
Dr Henrietta Campbell CB



Department of
**Health, Social Services
and Public Safety**

An Roinn

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

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URGENT COMMUNICATION

HSS(MD)7/2004

To: All General Practitioners (for cascade to practice nurses and non-principals working in your practice)
Community Pharmacists
Medical Directors of HSS Trusts for cascade to:
- Consultant Psychiatrists
- Consultant Clinical Psychologists
Directors of Public Health in HSS Boards
Directors of Pharmaceutical Services in HSS Boards (for cascade to prescribing advisers)
Directors of Pharmaceutical Services in HSS Trusts
Directors of Nursing in HSS Boards
Directors of Nursing in HSS Trusts (for cascade to Community Psychiatric Nurses)
GP Advisers in HSS Boards
Regional Medicines and Poisons Information Service

Castle Buildings
Upper Newtownards Road
STORMONT, BT4 3SQ
Tel: 02890520563
Fax: 02890520724
Email:
henrietta.campbell@dhsspsni.gov.uk

Your Ref:
Our Ref:
Date: 11 March 2004

Dear Colleague

PAROXETINE (SEROXAT) REMINDER TO USE THE RECOMMENDED DOSE

Attached is advice from the Professor Gordon Duff, Chairman of the Committee on Safety of Medicines, on the use of paroxetine (Seroxat) in adults.

Please report any suspected adverse reactions to paroxetine via the Yellow Card Scheme.

Yours sincerely

HENRIETTA CAMPBELL (DR)
CHIEF MEDICAL OFFICER

JUDITH HILL (MISS)
CHIEF NURSING OFFICER

NORMAN MORROW (DR)
CHIEF PHARMACEUTICAL OFFICER

cc: Director of Healthcare – PMS

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.

FROM THE CHAIRMAN, COMMITTEE ON SAFETY OF MEDICINES

Dear Colleague

PAROXETINE (SEROXAT) REMINDER TO USE THE RECOMMENDED DOSE

I wrote to you in June, September and December to inform you of advice of the Committee on Safety of Medicines (CSM) in relation to the use of selective serotonin uptake inhibitors (SSRIs) in children and adolescents with major depressive disorder.

Since then the Expert Working Group of the CSM has reviewed clinical trial data on the use of paroxetine (Seroxat) in adults.

A review of these data has confirmed that, as stated in the summary of product characteristics, 20 mg is the recommended daily dose in adults for the treatment of depression, social anxiety disorder (SAD), generalised anxiety disorder (GAD) and post traumatic stress disorder (PTSD). 40 mg is the recommended daily dose in adults for the treatment of obsessive compulsive disorder and panic disorder. There is no evidence from clinical trials that increasing the dose above the recommended dose increases efficacy in the treatment of depression, SAD, GAD, PTSD and panic disorder.

General prescribing advice for paroxetine:

1. Paroxetine should be prescribed at the recommended dose.
2. If your patient is being successfully treated at higher than the recommended dose, then this dose should be continued to the end of the planned course of treatment.
3. If your patient is being treated at higher than the recommended dose and is not doing well then a change of treatment should be considered.
4. There is evidence that attempts to escalate the dose rapidly are associated with an increased incidence of adverse events.
5. The adverse events that occur soon after starting therapy may be difficult to distinguish from the underlying condition. There is evidence that increasing the dose in this situation may be detrimental.
6. Patients taking paroxetine should not stop treatment suddenly. Any cessation of treatment should proceed by a gradual downward titration.

Further information

Further information for prescribers and patients including questions and answers and a summary of the dose response data for paroxetine is available on the website of the MHRA (<http://www.mhra.gov.uk>) and also on the public health link website (<http://www.info.doh.gov.uk/doh/embroadcast.nsf>)

Please report any suspected adverse reactions to paroxetine via the Yellow Card reporting scheme to the CSM/ MHRA.

Should you require any additional information, please telephone 020 7084 2000 at the MHRA.

**PROFESSOR GORDON DUFF
CHAIRMAN COMMITTEE ON SAFETY OF MEDICINES**