re:ACTION  No.26

December 2002

An occasional bulletin from the West Midlands Centre for Adverse Drug Reaction Reporting

Please let us know if you would like to receive this bulletin by email:
help@csmwm.org

RECENT REPORTS

Poisoned weeds (*Lancet.* 2002; **360**: 1884)

We have previously reported adverse reactions and interactions due to herbal preparations, such as St John's Wort. Herbal preparation can also be adulterated with more orthodox medicines.

A recent report in the Lancet describes a patient presenting with Cushing's disease following ingestion of a Chinese herbal preparation. Analysis of the preparation revealed the presence of alprazolam and betamethasone.

Health professionals should be aware that herbal preparations may contain orthodox drugs. The Regional Quality Control laboratory at City Hospital has recently tested samples of 'Wau Wa' cream, a 'Chinese' remedy for eczema that contained high concentrations of clobetasol. This product was being used in a child aged 18 months.

We would welcome any reports of adverse reactions, regardless of severity, related to herbal compounds and any suspicion of adulteration. The Regional Quality Control laboratory can analyze samples submitted.

Changes to the Yellow Card Scheme (*British Journal of Pharmacology* 1995: **40**:173-175)

In October, two changes were made to the Yellow Card scheme. Firstly, reporting was extended to all nurses, health visitors and midwives. Studies have shown that nurses can provide valuable reports and we would welcome and encourage nurses to make use of the Yellow Card Scheme.

Secondly, suspected adverse reactions can now be reported electronically via the CSM's webpage. Paper based Yellow Cards will continue to be important, but the new eYC (electronic Yellow Card) will be a convenient addition to the ways in which adverse drug reactions can be reported.

Links to the eYC and tips on reporting are available on our website at http://www.csmwm.org

PG tips – coxibs damage kidneys (*Drug Safety* 2002; **25(7)**:537-44)

Selective prostaglandin synthase (cyclo-oxygenase) inhibitors, such as celecoxib and rofecoxib have renal adverse effects similar to those of conventional non-selective NSAIDs. Both have been associated with serious or life-threatening renal failure after short-term therapy. Pre-existing renal impairment, increased age, heart failure, liver dysfunction, diuretic therapy and/or ACE inhibitors appear to increase the risk, but patients with normal renal function before treatment can also be affected.

We have received reports of renal failure with

several Cox-2 inhibitors (rofecoxib 6, celecoxib 1, parecoxib 1). A recent report is renal failure in a 91-year old woman who had been taking rofecoxib 12.5mg daily for arthritis.

We welcome reports of drug- induced renal damage.

Only when I stop… SSRIs

(*Pharmacoepidemiology and Drug Safety* 2002; **11(4)**:281-3)

A recent French study shows that withdrawal reactions are more likely with short half-life SSRIs, such as paroxetine and venlafaxine, than with other SSRI antidepressants, such as citalopram, escitalopram, fluoxetine, fluvoxamine, nefazodone or sertraline.

We have received reports of drug withdrawal reactions associated with the use of all SSRIs but the majority of them have been associated with the withdrawal of venlafaxine and paroxetine. The reactions generally start within a few days of stopping treatment and usually involve tremors, nausea, dizziness, headaches, and paraesthesia. We have received 3 reports of myoclonic jerks, heavy menstrual blood loss, and an increase in INR in patients who stopped taking SSRIs.

We welcome reports of withdrawal reactions related to drug therapy; it is especially helpful if details of the regimen required to wean the patient off the drug are included.

Warfarin worries with Cox-2 inhibitors

In *Re:ACTION 24* we highlighted the potential for rofecoxib and celecoxib to interact with warfarin.

We have recently received a report of an 85-year-old woman whose INR increased from 2.7 to 5.0 within 1 month of starting treatment with etoricoxib 60mg daily.

The manufacturers of etoricoxib advise that the INR should be closely monitored when etoricoxib is introduced, or the dose is changed, in patients taking warfarin.

We welcome any reports of suspected drug interactions, especially those involving warfarin, which can be clinically serious.

REPORTING TO CSM West Midlands

We welcome Yellow Card reports on all suspected adverse reactions to new (▼) drugs including vaccines and unlicensed herbal remedies and *all suspected reactions to all drugs used in children*, and on all serious or unusual reactions to well-established drugs. You do not have to be certain that a drug caused a reaction in order to report.

You can **download a copy of the redesigned yellow card in Adobe PDF format** from our website (http://csmwm.org).

Please send reports to: CSM West Midlands, Freepost SW2991, BIRMINGHAM, B18 7BR.
No stamp is needed. If you would like a supply of pre-addressed and reply-paid yellow cards, please contact the above address.

SOME ADDITIONS TO THE LIST OF INTENSIVELY MONITORED DRUGS

Approved name	Trade name	Indication
BCG vaccine	▼ BCG vaccine SSI®	New strain for active immunisation against tuberculosis.
ertapenem	▼ Invanz®	treatment of moderate to severe infections caused by susceptible strains
pimecrolimus	▼ Elidel®	mild to moderate atopic dermatitis (eczema)

The entire list of about 220 intensively monitored drugs can be obtained from the centre or on our website: http://csmwm.org. Please report **all** adverse reactions you suspect are due to intensively monitored drugs. Please send any comments to: Dr R E Ferner at CSM West Midlands, or email: r.e.ferner@bham.ac.uk