re:ACTION December 1998 No.16

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

This bulletin and other items of news about the Centre are available on the internet at http://www.chtpharm.demon.co.uk/csmwm.htm

REPORTING TO CSM West Midlands

We welcome Yellow Card reports on all adverse reactions to new (–) drugs including vaccines and unlicensed herbal remedies, and on all serious or unusual reactions to well-established drugs.
Yellow Cards can be found in the BNF, MIMS, the ABPI Compendium of Data Sheets, OTC Directory and in FP10 prescription pads. Further supplies can be obtained from CSM West Midlands.

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.

ADDITIONS TO CLOSELY MONITORED DRUGS include

Approved name	Trade name	Indication
– cefprozil	Cefzil®	mild to moderate infection
– clopidogrel	Plavix®	reduction in atherosclerotic events
– dorzolamide and timolol	Cosopt®	treatment of open angle glaucoma
– entacapone	Comtess®	adjunct to levodopa in Parkinson's disease
– orlistat	Xenical®	obesity
– propiverine	Detrunorm®	idiopathic bladder instability
– rizatriptan	Maxalt®	migraine
– sildenafil	Viagra®	erectile dysfunction
– tiagabine	Gabitril®	add-on therapy for seizure control
– zafirlukast	Accolate®	control of asthma

There are around 170 drugs on the closely monitored list. An up-to-date list can be obtained from the centre or on our internet site. Please report **all** adverse reactions you suspect are due to closely monitored drugs.

RECENT REPORTS

No go... urinary hesitancy with reboxetine

(*Br. J. Psychiatry* 1998: **173**: 441-2)

We have recently received two reports of urinary hesitancy associated with the use of reboxetine to treat depression. The first involved a 53 year-old man who developed symptoms 2 days after starting the drug and recovered 4 days after stopping treatment. The second concerned a 67 year-old man whose symptoms started immediately on taking the drug and stopped immediately on stopping treatment.

The first case report of urinary hesitancy with reboxetine has just been published. It details a 59 year-old man who started reboxetine 4 mg twice daily for depression and had symptoms of urinary hesitancy and inability to void his bladder completely. This patient stopped reboxetine after ten months' treatment, but restarted it when his depression recurred two weeks later, in conjunction with doxazosin 1 mg per day. His urinary symptoms did not recur. In this case it was a urologist who suggested that the urological symptoms may be related to reboxetine use. It is likely that

the urinary hesitancy is caused by the potentiation of sympathetically released noradrenaline in the urinary bladder. The -blockade by doxazosin seemed to have prevented a recurrence of symptoms on restarting the treatment.

We welcome reports of serious reactions to any drug especially to new or unusual adverse drug reactions.

Persistent loss of taste with terbinafine

(*Br. J. Dermatology* 1998: **139**; 747-8)

Taste disturbance, although a rare reaction, is one of the more commonly reported adverse effects of oral terbinafine use. This year we have received 3 reports of this reaction. In 2 of these cases there was no recovery after several weeks and the long-term outcome is unknown. In the third case there was a recovery in the sensation of taste after stopping the drug. In the majority of cases, however, the taste disturbance is transient.

A recent case report has detailed persistent taste loss in a 46 year-old woman who was taking oral terbinafine for toenail onychomycosis and suffered a complete loss of taste. She stopped taking terbinafine immediately but has only experienced a partial recovery in taste after 3 years. There was no other apparent cause for her persistent taste disturbance.

We welcome spontaneous follow-up information on previously submitted reports which add further information, or clarification. Please use the ADR report number when submitting such follow-up information.

No real alternative: new hazards of alternative medicines

(*New Eng. J. Med* . 1998; **339**: 839-41; 846-7; 785-91; 806-11)

A recent editorial in the New England Journal discussed the problems of alternative medicine: 'What most sets alternative medicine apart, in our view, is that it has not been scientifically tested and its advocates largely deny the need for such testing.' The reliance of alternative practices such as homeopathy on theory and anecdote, rather than rigorous evaluation means that we lack any clear measures either of their efficacy or of their safety. Their use is justified by case reports. These do not help to generate hypotheses that can be scientifically examined, as in conventional medicine, but are used as the sole basis for practice.

These reflections were stimulated by reports of a 15-year-old boy who was diagnosed as having Hodgkin's disease, but initially insisted on treatment with a mixture of the herb astragalus and dairy colostrum, with serious and predictable consequences; of a 9-year-old girl whose brain tumour was removed, but whose parents insisted she be treated with shark cartilage rather than adjuvant chemotherapy (she died); and of patients taking 'traditional Chinese medicines' adulterated with lead.

For good measure, the Journal also carried an article on 'PC-SPES', an alternative treatment for carcinoma of the prostate, which contained 8 herbs, including Panax pseudo-ginseng, and licorice. Analysis showed the remedy to contain potent, but unregulated, oestrogenic activity, responsible for breast tenderness and loss of libido in all 8 patients described, and venous thrombosis in one. The use of this unregulated mixture of herbs may confound the results of standard or experimental therapies, and may produce clinically significant adverse effects.

If this were not enough, there is a brief report from the Food and Drug Administration of two patients who developed digitalis toxicity after taking a herbal preparation for 'internal cleansing' that was contaminated with *Digitalis lanata*.

We welcome any reports of adverse reactions to 'alternative therapy' that can help define its safety.

Please send any comments, questions or suggestions to:

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