

An occasional bulletin from the West Midlands Centre for Adverse Drug Reactions 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, 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 Datasheet Compendium, OTC Directory and in FP10 prescription pads. Further supplies can be obtained from CSM West Midlands.

ADDITIONS TO CLOSELY MONITORED DRUGS include

- adapalene (Differin®)
- atorvastatin (Lipitor®)
- latanoprost (Xalatan®)
- fluorouracil & adrenaline (Accusite®)
- fexofenadine (Telfast®)

We are keen to receive reports of **all** suspected reactions to all closely monitored drugs, and to vaccines and unlicensed herbal preparations.

RECENT REPORTS

Formulating adverse effects

We have received a number of reports of adverse reactions occurring when a patient is given a different brand of the same drug. A yellow card reports tongue swelling after a patient used Glytrin[®] spray. This was not seen with previous use of Nitrolingual[®] spray. It is likely that the ethanol content of Glytrin[®] spray (96%) was responsible; Nitrolingual[®] is ethanol-free.

We have also received a report of a rash developing when a patient was switched from Nolvadex[®] to generic tamoxifen. Nausea and urticaria has been reported when a patient switched brands of nifedipine capsules, and a patient reported headaches when changing brands of slow release verapamil preparations.

Many formulation excipients cannot be considered to be inactive - indeed, they may be the primary cause for adverse reactions to the pharmaceutical dosage form. We welcome reports of adverse reactions to changes in dosage form, or to changes from one brand of a product to another. When the quality of a product is suspect, it can be examined in the Regional Quality Control laboratory. Contact Mitch Phillips, Regional QC Pharmacist, on 0121-507 5236 for further details.

Keeping abreast of eye changes... retinopathy and tamoxifen (*Am. J. Ophthalmol.* 1993; **116**: 372-3, *Cancer* 1992; **69**: 2961-4)

We have received a report of retinopathy associated with tamoxifen use. Tamoxifen use has been associated with corneal opacities, decreased visual acuity and retinopathy. These problems are generally seen after at least 12 months of therapy and have been reported at low (20mg daily) and high doses (up to 180mg daily). Retinal findings appear as superficial refractile deposits in the posterior pole, primarily in the perimacular area.

We welcome the reporting of serious reactions to well-known drugs.

A close shave... warfarin induced alopecia (ADRB 1995; **173**: 655-8)

We have recently received a report of a patient who developed a localised alopecia of the beard area after several months of stable warfarin treatment.

Diffuse alopecia, primarily affecting the scalp is said to occur in up to 40% of patients treated with warfarin. The hair loss begins within a few weeks of therapy. There have only been thirty-three reports of warfarin induced alopecia to the CSM since 1964, although only 4 of these reports specifically mentioned a localised alopecia.

Deadly nightshade?.. adverse effects of unlicensed herbal remedies (*ADRB* 1997; **183**: 695-8, *Current Problems* 1996; **22**: 10)

We have recently received a report of a young woman who reported to her GP with chronic diarrhoea and severe iron deficiency anaemia. She had been taking an unlicensed herbal preparation which was listed as containing absinthe, *Artemisia absinthium*.

As well as causing adverse reactions directly, herbal preparations may interact with certain medicinal products. For instance gugulipid (derived from an ancient Indian medicinal plant *Commiphora mukul*), reduces the bioavailability of diazepam and propranolol by one-third. Another serious problem is that herbal and traditional remedies may be contaminated with toxic metals, alkaloids, or pathogenic micro-organisms. There have been at least five cases in recent years of patients in the West Midlands region who have taken traditional remedies which contained soluble lead and sometimes other heavy metals.

The MCA has recently extended the "Yellow Card" reporting scheme to cover unlicensed herbal and traditional medicines, and we welcome any reports of adverse reactions to any herbal product or traditional medicine. Please enclose details of the product's ingredients if possible. In the case of serious reactions, a sample for testing would be welcomed.

Please send any comments, questions or suggestions to: Dr R E Ferner, CSM West Midlands, City Hospital, Dudley Road, BIRMINGHAM B18 7BR or email: r.e.ferner@bham.ac.uk