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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

RECENT REPORTS

More than topical... anaphylaxis with chlorhexidine

(*Contact Dermatitis* 1999; **40**: 215)

A 33 year old man experienced an anaphylactic reaction after applying chlorhexidine 0.6% to a rash on his buttocks. Within minutes, he had developed generalised urticaria, dyspnoea and loss of consciousness. He was treated with subcutaneous adrenaline and iv corticosteroids and recovered. This is the first reported case in the literature of anaphylaxis after application of chlorhexidine to unbroken skin. At CSM West Midlands we have received 1 report of mucosal irritation after application of chlorhexidine mouthwash, and 2 further reports of mouth oedema and bronchoconstriction. In one of these a 63 year old man had washed his dentures in Hydrex® containing chlorhexidine 0.5% on two occasions and each time suffered mouth oedema and bronchoconstriction. In the other, a woman had a mild systemic reaction after using Corsodyl® mouthwash. She was treated in casualty.

Although these reactions are rare, they illustrate the possible severe systemic effects of topical preparations. We welcome reports of any serious reactions to topical application of medicines.

Community pharmacist reporting

The west Midlands was one of the pilot sites for the community pharmacist reporting scheme for adverse reactions. The reports we receive continue to be appropriate and of high quality. Over half of them relate to OTC products, and might otherwise go unnoticed.

The pilot study was judged successful. From November all community pharmacists will be able to report adverse drug reactions in the usual way using the specially printed AR20 forms, or they may use the forms in the current copy of the BNF (No 38). Please note that when using the BNF forms, although the GP's details should be given there is no need to get the GP's signature.

We welcome any reports which meet the reporting protocol, especially to herbal preparations and OTC products. Staff at the centre are available to run training sessions for groups of community pharmacists.

Problems with NSAIDs

We have received 21 reports concerning rofecoxib since its launch during the summer. Over half of these relate to the GI tract, but only four of the reports concern serious reactions - a 78 year old man developed depression and dizziness after 5 weeks treatment with rofecoxib. A 59 year old man with osteoarthritis developed joint inflammation 2 days after starting treatment with rofecoxib. A 55 year old man developed phlebitis after 5 weeks treatment with rofecoxib. In these 3 cases the outcome is unknown. In the last case a 56 year old woman suffered dyspnoea whilst taking rofecoxib for 2 weeks.

In the same period we received 7 reports of reactions to other NSAIDs, all of which were serious. In five of these cases the reactions were well-documented in the literature.

We encourage reporters to report any reaction, however trivial, to the intensively monitored NSAIDs aceclofenac, meloxicam and rofecoxib, and to remain vigilant in reporting **serious** or unusual reactions to the older NSAIDs even if the reaction is well recognised.

Coming unstuck... neurotoxicity from a tissue sealant

Quixil® is a biodegradable surgical adhesive which has haemostatic, binding and sealant properties. It is based a concentrate of several human clotting proteins, including thrombin. The 'clot' formed is metabolized naturally over several days, allowing tissues time to heal. Rather like epoxy resin, it comes as two components in separate vials. The components are mixed as they pass down the applicator. Although the

manufacturers have suggested that Quixil could help in a variety of circumstances where sutures and clips are used, the product is only licensed for facilitating haemostasis and reducing bleeding during liver surgery.

Two reports of fatal neurotoxic reactions associated with Quixil's (unlicensed) use in neurosurgical procedures have been received by the Committee on Safety of Medicines since the product was licensed last month. The Committee has stressed the need to avoid circumstances where Quixil might come into contact with the CSF or dura mater, as could happen in neurosurgery and spinal surgery.

Unexpected adverse effects are one of the dangers of new products, especially if their use is extended to areas not assessed in clinical trials. We are keen to receive reports of serious or unusual reactions to all medicines, whether used for indications covered by the Marketing Authorization ('Product Licence') or not. All such reports are confidential.

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, occasional MIMS, and the ABPI Compendium of Data Sheets, OTC Directory. 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 INTENSIVELY 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
felodipine and ramipril	▼ Triapin®	treatment of hypertension
orlistat	▼ Xenical®	obesity
propiverine	▼ Detrunorm®	idiopathic bladder instability
quinupristin and dalfopristin	▼ Synercid®	treatment of Gram-positive infections when no other treatment option is appropriate
rizatriptan	▼ Maxalt®	migraine
rofecoxib	▼ Vioxx®	symptomatic relief in osteoarthritis
sildenafil	▼ Viagra®	erectile dysfunction
tiagabine	▼ Gabitril®	add-on therapy for seizure control
zafirlukast	▼ Accolate®	control of asthma

There are around 170 drugs on the intensively monitored list. An up-to-date list can be obtained from the centre or on our website: http://www.chtpharm.demon.co.uk/csmwm.htm. Please report **all** adverse reactions you suspect are due to intensively monitored drugs.

Please send any comments, questions or suggestions to:

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