

# *re:ACTION* January 1995 No.6

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

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## REPORTING TO CSM West Midlands

**We welcome Yellow Card reports on all adverse reactions to new ( - ) drugs and on all serious or unusual reactions to well-established drugs.**

Yellow Cards can be found in the BNF, MIMS, the ABPI Datasheet Compendium and in FP10 prescription pads. Further supplies can be obtained from CSM West Midlands.

Please send reports to

CSM West Midlands Freepost BIRMINGHAM B15 1BR.

No stamp is needed.

## ADDITIONS TO CLOSELY MONITORED DRUGS include

- fentanyl patch (Durogesic®)
- nicorandil (Ikorel®)
- quinagolide (Norprolac®)
- ceftibuten (Cedax®)
- carvedilol (Eucardic®)
- venlafaxine (Efexor®)

## RECENT REPORTS

### **Bladder trouble ... haemorrhagic cystitis caused by tiaprofenic acid**

(Mayall et al., *BMJ* 309:599-600, 1994; Harrison et al., *BMJ* 309:574, 1994, *Current Problems*, 20:12-16)

Haemorrhagic cystitis is an unpleasant and troublesome disorder. It can occur with cyclophosphamide chemotherapy, when a reactive metabolite is excreted in the urine. The incidence in that case can be reduced by concurrent administration of mesna. Other drugs are rarely considered in the differential diagnosis.

Recently, two groups in this country have reported 12 cases of interstitial cystitis presenting with frequency, suprapubic pain, and haematuria. Three of the patients underwent total cystectomy, and a fourth had other major bladder surgery. It eventually transpired that all 12 patients had been taking the non-steroidal anti-inflammatory drug tiaprofenic acid, and that patients improved on stopping the drug. Subsequent retrospective analysis of CSM data showed that cystitis, haematuria or dysuria accounted for 2.6% of all reports of adverse

reactions to tiaprofenic acid, but only 0.03% of all reports to other non-steroidal anti-inflammatory drugs. The Australian ADR service received 47 reports of cystitis with tiaprofenic acid, compared with 3 to all other non-steroidal agents.

Tiaprofenic acid is a cause of haemorrhagic cystitis. Patients should not be given it without good reason, and should be told of this complication. Since these articles appeared we have received 3 Yellow Card reports of cystitis and haematuria related to the drug.

### **Collapse over the counter - paracetamol and anaphylaxis**

(Leung et al., *Clinical and Experimental Allergy* 1992; **22**: 831; Aronson *BMJ* **308**:1140-1141, 1994; )

We have recently received a Yellow Card report of anaphylaxis related to the ingestion of paracetamol as "Anadin® Paracetamol".

Allergic reactions to paracetamol are very rare, but several cases are described in the literature. Bronchospasm, angioedema, urticaria, hypotension and collapse have all been reported. In one series of 5 patients, 4 were able to take aspirin without ill effect, but the fifth developed urticaria when challenged with aspirin, as well as with paracetamol. There is no information on the safety of opioids in these patients. The mechanism is presumably immunological, but this has not been proven.

As a coda to this, it is perhaps worth pointing out that the BNF lists Anadin®, Anadin® Extra, Anadin® Extra Soluble, Anadin® Paracetamol and Anadin® Ibuprofen. Anadin® Extra and Anadin® Extra Soluble contain both paracetamol and aspirin. Similar confusion arises with Aspro® and Beechams® preparations.

We welcome reports of serious adverse reactions to well-known drugs.

### **Reacting to the Chief Medical Officer ... Measles and Rubella vaccine**

The threat of an epidemic of measles in a largely unexposed and underimmunized population of schoolchildren led the Government to institute a campaign of mass immunization. The costs and benefits of such a large undertaking are sometimes difficult to measure. The Chief Medical Officer asked that any adverse reaction be notified, using the Yellow Card Scheme. In several health districts, the Yellow Cards accompanied the batches of vaccine, so that they were immediately available if any problem became apparent.

We received over 70 Yellow Cards relating to Measles and Rubella Vaccine. No fatal reactions were reported, and most were brief and relatively minor. These included local reactions, fever and minor rashes. There were 11 reports of urticaria, including one of urticaria and wheeze. The most serious reactions were anaphylaxis and collapse, though it seems likely that several of the episodes of collapse were related to vaso-vagal faints.

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Please send any comments, questions or suggestions to: Dr R E Ferner, West Midlands Centre for Adverse Drug Reactions Reporting, City Hospital, Dudley Road, BIRMINGHAM B18 7QH