

re:ACTION May 1994 **No.4**

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

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

- famcyclovir (Famvir⁷)
- fosfomycin (Monuril⁷)
- dornase alfa (Pulmozyme⁷)
- cabergoline (Dostinex⁷)
- poractant (Curosurf⁷)
- lansoprazole (Zoton⁷)

RECENT REPORTS

Down in the mouth ... oral manifestations of adverse drug reactions

(Adverse Drug Reactions in Dentistry. Seymour and Walton, OUP 1988)

We have had several reports recently of drug-induced oral disease. Both increase and decrease in salivary flow can be due to drugs, and we have had reports of dry mouth associated with paroxetine (Seroxat[®]), a recognized complication of that drug. Doctors have also sent Yellow Cards describing hypersalivation with clozapine (Clozaril[®]), and with fluvoxamine (Faverin[®]). The former reaction, but not the latter, is mentioned in the data sheet. The CSM has now had 5 reports of hypersalivation with fluvoxamine, suggesting that it may not be a chance association.

We have also heard of oral ulceration associated with carteolol (Teoptic[®]) eye drops, with diclofenac and with trimethoprim. Drugs with a local irritant effect, including non-steroidal agents like diclofenac, are well-known causes of mouth ulcers, which can also indicate neutropenia caused by drugs such as carbimazole.

Gum hypertrophy has been reported in a woman treated for epilepsy with carbamazepine plus primidone. This is interesting, because the reaction is common with phenytoin but not well-recognised with other anti-epileptic drugs. It can also occur with nifedipine, the oral contraceptive,

and cyclosporin.

More unusual still are reports of uvular oedema with oxybutynin and of loss of the primary dentition with sodium valproate plus vigabatrin treatment.

We welcome all reports from doctors and dentists of serious or unusual oral adverse reactions.

Fire in the belly ... pancreatitis from mesalazine

(Adverse Drug Reaction Bulletin, April 1994; see also Current Problems in Pharmacovigilance Vol 20: 2-3; NEJM 1994; 330: 1198)

A surgeon has recently reported to us a case of a 25-year old man who developed acute pancreatitis a few weeks after starting treatment with mesalazine (Asacol®) for ulcerative colitis. He made a good recovery.

Recent reviews have dealt with adverse reactions to the aminosalicylates used to treat ulcerative colitis, and to drug-induced pancreatitis and acute pancreatitis. There are now several reports in the literature of mesalazine-induced pancreatitis, and a few of pancreatitis associated with sulphasalazine. Cases have usually occurred within 3 weeks of the start of treatment. The pancreatitis is usually not severe, and settles when treatment is stopped. "Pancreatitis should be suspected in patients under treatment with 5-aminosalicylic acid drugs who develop a new type of abdominal pain". The 5-ASA drugs can also cause nephrotoxicity, pulmonary fibrosis and polyarteritis in rare cases.

Other drugs associated with acute pancreatitis include aspirin, azathioprine, cimetidine, didanosine, erythromycin, frusemide, methyldopa, metronidazole, nitrofurantoin, oestrogens, paracetamol, pentamidine, ranitidine, sodium valproate, sulindac, sulphonamides, tetracyclines, and thiazide diuretics.

Acute pancreatitis associated with drug therapy is perhaps more common than previously realized, and we would be pleased to have any reports of possible cases.

Beating the bounds ... the problem of "licensed indications"

(Drugs & Therapeutics Bulletin 1992, **30**: 97-99)

The product licence is granted to the manufacturer of a medicine and determines the way in which he can market his product.

In several areas of medicine, most notably paediatrics, doctors find that manufacturers have not asked for licences covering the indication for which they use the drug.

Doctors sometimes worry that they may be censured if they report adverse reactions to drugs used outside the manufacturer's product licence. All Yellow Card reports are confidential, and doctors should not be dissuaded from reporting a reaction to a drug used outside its licence.