

re:ACTION January 1996 **No.9**

*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, 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. This address has changed and will appear on future yellow cards. The old address can still be used until March 1996. If you would like a supply of pre-addressed and stamped yellow cards, please contact the above address.

ADDITIONS TO CLOSELY MONITORED DRUGS include

- | | |
|------------------------------|---------------------------|
| – eformoterol (Foradil®) | – anastrozole (Arimidex®) |
| – alendronic acid (Fosamax®) | – topiramate (Topamax®) |
| – cladribine (Leustat®) | – dorzolamide (Trusopt®) |

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

RECENT REPORTS

Outside permitted limits... Extravasation causing cancer

(New England Journal of Medicine 1995; 332: 754)

Ten years after inadvertent leakage of an infusion of doxorubicin that caused local skin necrosis, a woman presented with a squamous cell carcinoma in an ulcer at the site of the original wound. The doxorubicin had been part of treatment for adenocarcinoma of the stomach. When the skin necrosis occurred, the woman had declined surgery. It is not clear whether the cancer was due to mutagenic damage from the doxorubicin, or to the long-standing ulcer.

It is often difficult to establish adverse effects that occur a substantial time after exposure to a drug. We welcome any reports of suspected delayed reactions.

Pain killers - a headache.... Analgesic drugs can cause headache

(British Medical Journal 1995, 310: 479-80)

Adverse drug reactions stand out if they present very differently from the disease being treated. It is much harder to believe that a drug can reproduce or exacerbate the symptoms for which it has been administered. Drug-induced headache can be especially difficult to disentangle from natural disease. For example, ergotamine can cause severe headache if migraine sufferers take it repeatedly; also, sudden

withdrawal of ergotamine can precipitate severe migraine. Indomethacin, ketorolac, and other non-steroidal drugs can cause headache; and aseptic meningitis may occur with ibuprofen.

Over a quarter of migraine sufferers in one study were taking aspirin or paracetamol, or both, each day, and two-thirds improved when the analgesics were stopped.

Drug induced illness can prolong or mimic the condition for which treatment was given initially.

Safer but not safe... Even low dose aspirin prophylaxis increases the risk of gastrointestinal bleeding

(British Medical Journal 1995, 310: 827)

Non-steroidal anti-inflammatory drugs in analgesic dosage increase the risks of bleeding from peptic ulcers. Aspirin is now widely used to reduce the risks of cardiovascular disease after transient cerebral ischaemia, stroke, and myocardial infarct. The dosage used is commonly between 75mg and 300mg daily. A recent paper has examined the probability of aspirin usage in 1121 patients with bleeding from a peptic ulcer, and suitable control groups. The odds ratios suggest that patients with bleeding were twice as likely as controls to be taking 75mg daily; 3 times as likely to be taking 150mg daily; and 4 times as likely to be taking 300mg daily.

Even low dosages do not guarantee safety, but they reduce the risks. Nevertheless, the low risk of GI bleeding is normally well compensated for by the benefits of reducing the risks of cardiovascular disease.

Spot the adverse reaction... Minocycline can cause pulmonary eosinophilia, hepatitis and a lupus-like syndrome

(British Medical Journal 1995; 310: 1520 and 1996; 312: 169)

Four patients developed respiratory symptoms, abnormal chest X-rays, and eosinophilia, within a week or two of starting minocycline treatment for acne. Three reported fever or night sweats. All recovered after the drug was stopped. Two patients who had been exposed twice were ill on both occasions.

Another series of 7 patients treated with minocycline suffered arthritis and hepatitis, and had a positive antinuclear antibody. The CSM had received 8 reports of drug-induced lupus associated with minocycline exposure and 15 of hepatitis.

Rare but serious reactions can have an important influence on prescribing decisions for common but benign conditions such as acne. We welcome reports of serious adverse reactions that you suspect might be due to a drug, even if the effects are well-described.

Foil safe?

(Lancet 1995; 346: 1308)

Adverse effects cannot always be attributed directly to the medicine itself.

A 68 year old man, diagnosed clinically as suffering from a perforated appendix, underwent laparotomy. Peritonitis due to an ileal perforation was found, and the ileum resected. The pathologist examining the resected specimen retrieved a tablet still in its blister pack: the sharp corner of the plastic/foil package was responsible for the perforation.

The safe administration of medicines demands care at every stage.

Please send any comments, questions or suggestions to: Dr R E Ferner, CSM West Midlands, City Hospital, Dudley Road, BIRMINGHAM B18 7BR