

re:ACTION January 1994 **No.3**

*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 unexpected 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.

CLOSELY MONITORED – DRUGS - a reminder

Nearly seventy new drugs are closely monitored by the CSM, and are marked with a ?.
The latest additions include :

- levonorgestrel (Norplant®)
- apomorphine (Britaject®)
- alfuzosin (Xatral®)
- rifabutin (Mycobutin®)
- lacidipine (Motens®)

RECENT REPORTS

Spin-crack ... inhaler capsule fractures

We have received a report of an unusual adverse reaction to drug therapy by inhaler. A 9-year old girl taking sodium cromoglycate (Intal Spincap®) breathed in a part of the hard gelatin capsule which contains the powder when the capsule shell cracked in the inhaler. It seems that the gelatin had become brittle. Fortunately, there was no immediate harm, but she has now stopped using sodium cromoglycate.

In the past, attention has been drawn to the danger of inhaling the cap over the mouth-piece of an inhaler, and these caps are no longer made in transparent plastic.

We are interested in any reports of unusual reactions, including "mechanical" reactions.

Topical drugs ... systemic reactions

(BMJ 1994; 308: 110)

Topically applied non-steroidal anti-inflammatory drugs have to be absorbed to exert their therapeutic effect, so they can also produce systemic adverse effects.

Renal disease from the topical non-steroidals piroxicam (Feldene®) and benzydamine (Difflam®) has been reported in two patients, one of whom required dialysis for interstitial nephritis with nephrotic syndrome, a combination which the authors regard as indicating renal damage from non-steroidal drugs.

CSM West Midlands has received a report of a patient whose nocturnal asthma was worse whenever she had used felbinac gel (Traxam®) the day before. We would welcome further reports of systemic adverse effects to topical non-steroidal preparations.

Neutropenia ... New causes and old

CSM West Midlands has recently had reports of neutropenia or leucopenia associated with several drugs. We cannot be certain that the drugs caused the neutropenia or leucopenia, but detailed Yellow Card reports will be of help in defining the problems. Reports have mentioned:

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|----------------------------------|------------------|
| ciprofloxacin | interferon gamma |
| flucloxacillin with fusidic acid | lofepramine |
| fluoxetine | remoxipride |

The CSM has drawn attention to the problem of aplastic anaemia with remoxipride, and of drug-induced neutropenia, in the latest edition of Current Problems in Pharmacovigilance.

We encourage you to report to us any serious reaction such as neutropenia that could be due to a drug. It is helpful if results of investigative findings such as white cell counts are included.

Jekyll and Hyde ... clozapine in schizophrenia

(New Eng J Med 1993; 329: 162-7; Am J Psy 1993; 150: 985-6; Am J Psy 1993; 150:1128)

Clozapine (Clozaril®) is "superior to standard antipsychotic drugs in the treatment of refractory schizophrenia", but has a number of side-effects, especially agranulocytosis, which occurs in about 1% of patients. The manufacturers therefore monitor the white cell count in all patients, in the mandatory Clozaril Patient Monitoring Services (CPMS).

Other less common side-effects that have been reported include a toxic hepatitis which resolved within one month of stopping the drug, and myoclonic epilepsy that became secondarily generalized. We should welcome reports from psychiatrists and others on this or other newer agents.

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