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

Yellow Card Centre West Midlands ***http://www.adr.org.uk***

If you would like to receive this bulletin by email contact: help@csmwm.org

Pisa syndrome: an antipsychotic dystonia

(*The Journal of Neuropsychiatry and Clinical Neurosciences* 2003;**15(4)**:458)

Pisa syndrome is a rare disorder associated with antipsychotic drugs, and more rarely with other drugs such as anti-cholinesterases and antiemetics. It is manifest as a sustained involuntary flexion of the body with a slight rotation of the trunk. The patient's head may lean to one side – hence the link to the 12th century *Torre pendente di Pisa*.

More common in females and older patients with neurodegenerative disorders, its onset can be insidious, or follow the addition of a new anti-psychotic to an established regime.

Ziegenbein et al. report Pisa syndrome in a 38-year-old woman. The patient discontinued clozapine, because of adverse effects, and began treatment with ziprasidone. After three weeks of treatment, she developed a predominately unilateral acute truncal dystonia. Symptoms improved 14 days after discontinuation.

Dystonic reactions to drugs are serious reactions and should be reported to the Yellow Card scheme.

Recent changes to the Yellow Card scheme

Since our last newsletter there have been some changes to the Yellow Card scheme. Firstly, *The Committee on Safety of Medicines* has now been replaced by the *Commission on Human Medicines*, so our alternative name of *CSM West Midlands* has now been changed to *Yellow Card Centre West Midlands*. From May 2006, all Yellow Cards have been processed at a central location for CHM/MHRA.. For this reason, we have styled ourselves: *West Midlands Centre for Adverse Drug Reactions*. In the case of reports that require further clinical information, our unit will continue to be the point of contact with reporters.

We will also continue to be available for reporters in the region, to answer queries relating to adverse drug reactions and the reporting scheme, and to provide education and locally-based research in the field of drug safety. You can learn more about our activities at our new web domain www.adr.org.uk

Sharing our expertise

Do you need a speaker for an educational event, or a lunchtime meeting? Our Centre is keen to promote the Yellow Card scheme, and can provide training on adverse drug reactions, the Yellow Card scheme, and related subject areas - such as medical error.

If you would like to discuss this with us, please ring 0121 507 5672 or email help@adr.org.uk

If you make one report this year…

…make it to a black triangle ▼ drug. A new drug's safety record is provisional. A drug is tested in a limited number of people; approximately 2500 patients are exposed, before marketing. This means that uncommon or rare adverse effects can be missed.

Your reports of suspected reactions to new drugs are crucial to providing safe and effective drug therapy to patients. Yellow Card reports inform decisions that lead to changes in safety information, changes to drug licences and on rare occasions the withdrawal of medications.

Aid on NSAIDs

The MHRA and EMEA have recently published information about the cardiovascular risks of NSAIDs. In brief, non-selective NSAIDs may be associated with a small increase in the risk of thrombotic events – such as heart attack or strokes, although the exact risk may vary between medicines: Diclofenac has thrombotic risks similar to etoricoxib, but naproxen has lower thrombotic risks than the coxibs. Ibuprofen may have a small risk at high doses, but a risk at OTC doses taken for short periods is very unlikely.

The MHRA suggest that when prescribing NSAIDs or coxibs, prescribers should:

- Prescribe the lowest dose for the shortest period necessary.
- Consider the safety profile of an individual drug and the individual patient's risk factors (both cardiovascular and gastrointestinal).
- Switch drugs, only after careful consideration of the safety profile of the drug, and the patient's risk factors and personal preference.
- Prescribe concomitant NSAIDs and aspirin only if absolutely necessary.

A link to the full MHRA guidance can be found on our Drug Safety News:

http://adr.org.uk/drugsafety/?p=75

Lamotrigine and birth defects

The FDA suggests a possible association between exposure to lamotrigine monotherapy exposure during the first trimester of pregnancy and the development of cleft palate/cleft lip. The association is based on data from the North American Antiepileptic Drug Pregnancy Registry.

Although the clinical significance is still uncertain, the FDA has issued advice to patients that they should consult their doctor if they are taking lamotrigine and are pregnant or thinking of becoming pregnant, and also before stopping or starting to use lamotrigine. Further links to information from the FDA and the manufacturer related to this potential risk is linked to at our Drug Safety News page at: http://adr.org.uk/drugsafety/?p=76

The available data have been considered by the UK Commission on Human Medicines' Pharmacovigilance Expert Advisory Group and within Europe. Following these reviews, in June 2006, relevant healthcare professionals in the UK were informed of these new data and the implications they have for prescribing advice. The product information for all lamotrigine products is being amended to reflect these new data.

The birth defects caused by thalidomide were the trigger behind the formation of the Yellow Card scheme. We are keen that if you suspect a birth defect caused by drug exposure, you send a Yellow Card report.

Combining antithrombotics: a bleed may follow

(BMJ, doi:10.1136/bmj.38947.697558.AE published 19th September 2006))

A case-control study from Denmark has attempted to assess the risks of serious upper gastrointestinal bleeding from antithrombotic agents – used alone or in combination.

Aspirin, dipyridamole and warfarin approximately doubled the risk of a serious upper GI haemorrhage. Clopidogrel showed no significant increase in the risk of bleeding, although the 95% confidence intervals did not exclude the potential for a similar risk to the other antithrombotics.

Combined usage of drugs increased the risk of serious upper gastrointestinal bleeds significantly. Clopidogrel and aspirin in combination increased the risk sevenfold, and warfarin and aspirin fivefold.

Any case of bleeding is reportable to the Yellow Card scheme.

We encourage Yellow Card reports to all suspected adverse reactions to new (▼) drugs including vaccines and unlicensed herbal remedies and *all suspected reactions to all drugs used in children*, and on all serious or unusual reactions to well-established drugs. You do not have to be certain that a drug caused a reaction in order to report.

Please send reports to: Medicines and Healthcare products Regulatory Agency, CSM, Freepost, London, SW8 5BR.
If you would like a supply of pre-addressed and reply-paid yellow cards, please contact us:
Phone: 0121 5075672 **Email**: help@adr.org.uk

SOME ADDITIONS TO THE LIST OF INTENSIVELY MONITORED DRUGS

Approved name	Trade name	Indication
Insulin human powder for inhalation	▼ Exubera	Diabetes
Salmeterol	▼ Serevent Evohaler	Asthma, COPD

Please send any comments to: Dr R E Ferner at: r.e.ferner@bham.ac.uk