CSM/89/1/44

COMMITTEE ON SAFETY OF MEDICINES

CURRENT PROBLEMS

NUMBER 24 JANUARY 1989

Tabled Paper 4

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PARENTROVITE & ALLERGIC REACTIONS

Parentrovite (Bencard) ampoules contain high doses of Vitamin B and the C group vitamins together with metabisulphite for intravenous or intramuscular administration.

Between 1970 and July 1988 the Committee received 90 reports of adverse reactions associated with Parentrovite. 21 of these were received in 1987. 78 suspected reactions occurred during or shortly after intravenous injection, the remaining 12 after intramuscular injection. The most frequent reactions included 41 cases of anaphylaxis (2 of these were fatal), 13 cases of dyspnoea or bronchospasm, and 22 cases of rash or flushing. Previous uneventful exposure was noted in 5 cases.

Doctors are reminded that potentially serious allergic adverse reactions may occur during, or shortly after, the administration of Parentrovite.

It is recommended that:

- Parentrovite use is restricted to patients in whom parenteral treatment is essential.
- When given intravenously it should be administered by slow (10 minutes) infusion.
- Facilities for treating anaphylaxis should be available when Parentrovite is administered.

FENBUFEN, RASH AND PULMONARY EOSINOPHILIA

The Committee has received 7 reports of a suspected association between a rash and an allergic interstitial lung disorder in patients undergoing treatment with fenbufen (Lederfen-Lederle)

All cases developed a widespread rash (in four cases within 2 weeks of starting fenbufen) that heralded a more generalised illness comprising cough, fever, malaise and breathlessness requiring

admission to hospital. A diagnosis of pulmonary eosinophilia was made in 5 cases; all 5 had osteoarthritis. The remaining 2 reports concerned the appearance of an "allergic alveolitis" associated with the use of fenbufen; one of these cases was seropositive for rheumatoid arthritis. All patients recovered within 4-6 weeks of stopping fenbufen.

Rashes are frequently reported in patients receiving fenbufen (see "Current Problems 23") and, in a small proportion of cases, this reaction may be followed by a severe illness characterised by an allergic alveolitis or a pulmonary eosinophilia.

NEFOPAM HYDROCHLORIDE (ACUPAN)

The Committee has received 53 reports where nefopam (Acupan – Riker Laboratories) was associated with the development of urinary retention or the symptoms of hesitancy, poor stream or dribbling. In only one case was there a previous history of prostatism and all cases recovered on stopping nefopam.

A further 12 reports of confusion and 22 of hallucinations have also been received.

Nefopam should be used with caution in the elderly, in patients with symptoms of urinary retention, or when administered concurrently with other medications possessing anticholinergic activity.

NEW DRUGS – THE BLACK TRIANGLE SCHEME

New drugs undergoing intensive surveillance are identified by a black triangle symbol on all prescribing information. This includes their entries in MIMS, the British National Formulary, ABPI Data Sheet Compendium, loose data sheets and all advertisements. Black triangles are now normally removed after two years unless the Committee has a particular concern about a product's safety.

We ask doctors to report all suspected adverse reactions to new drugs in order to acquire knowledge about their adverse effects as quickly as possible. Full details of what to report appear below.

A list of black triangle drugs is enclosed so that it can be kept at hand in the surgery, ward or outpatient clinic. We hope that this will remind doctors of those drugs which require special reporting. The list will be revised and distributed in 'Current Problems' on a regular basis.

Adverse Drug Reactions: What to Report

NEW Drugs ▼

Report **ALL** suspected reactions, that is any adverse or unexpected event, however minor, which could conceivably be attributed to the drug.

Please report even if the reaction is well recognised or if you are unsure of the causal relationship.

New drugs have an inverted black triangle '▼' in the British National Formulary, MIMS and the Data Sheet Compendium.

ESTABLISHED Drugs

Report **SERIOUS** suspected reactions, including those which are fatal, life-threatening, disabling, incapacitating, or which result in or prolong hospitalisation.

Please report a serious reaction even if it is already well-recognised.

Please do *not* report *minor* reactions for established drugs.