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WHO Pharmaceuticals Newsletter

Nos. 7&8, July&August 1997

Regulatory actions

[Unrelated Sections Omitted]

Droperidol - revised data sheet : cardiac arrhythmias

France. The Medicines Agency has revised the data sheet for pharmaceutical products containing droperidol (DroleptanR : Janssen-Cilag) following a national enquiry that examined 26 reports of sudden deaths and cardiac arrhythmias associated with its use since its commercialisation in 1967. The deaths occurred within 15 minutes of administration in 10 cases, and acute alcoholism was reported in 11 cases.

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The dosage used was 15 ml at 100 mg (intramuscular), whereas the dosage currently prescribed for agitation is 10 mg to be repeated every 4 to 6 hours as necessary.

The incidence of sudden deaths is estimated as 1 per 55,000 vials.

The results of studies show that a dosage of 5 mg is sufficient for the treatment of agitation, therefore it was proposed to decrease the recommended dosage to 5 mg and to revise the product information to include a clear statement of the risk factors of increase in QT interval and cardiac arrhythmias and by strengthening the warning for alcoholic patients.

Moreover, an injectable dose of 2 ml at 2.5 mg/ml will rapidly be made available to physicians and will replace the 10 ml at 5 mg/ml vial in order to facilitate compliance with the recommended dosage.

A "Dear Doctor" letter has also been sent to prescribers.

Reference: Communication from the Agence du Médicament, 7 May 1997.