

DAPSONE (Group 3)

A. Evidence for carcinogenicity to humans (*inadequate*)

Cases of cancer have been reported in patients treated with dapsone for dermatitis herpetiformis¹ and leprosy². Several follow-up studies have been undertaken of patients with leprosy, some of whom were treated with dapsone^{1,3-6}. Increased mortality from cancer, restricted to males (standardized mortality ratio [SMR], 1.5; 95% confidence interval, 1.1-1.9), has been observed only in the most recent of them. The excess was most evident for cancers of the oral cavity and bladder and for lymphoma in males (SMRs, 4.5, 4.0 and 3.0, respectively) and for dapsone users. Possible confounding effects of tobacco and alcohol intake could not be addressed, but there was no substantial increase in mortality from lung cancer⁶.

B. Evidence for carcinogenicity to animals (*limited*)

Dapsone has been tested by oral administration in mice and rats, by intraperitoneal administration in mice and by prenatal and lifetime oral exposure in mice and rats. In three different studies in rats, high doses of dapsone induced mesenchymal tumours of the spleen in males (and of the peritoneum in two studies). An increased incidence of tumours of the thyroid was found in rats of each sex in one study and in males in a further study. The experiment in mice involving intraperitoneal administration of dapsone could not be evaluated. The other two experiments in mice did not provide evidence of carcinogenicity¹.

C. Other relevant data

No data were available on the genetic and related effects of dapsone in humans. It was not mutagenic to bacteria⁷.

References

¹IARC Monographs, 24, 59-76, 1980

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- ⁴Kolonel, L.N. & Hirohata, T. (1977) Leprosy and cancer: a retrospective cohort study in Hawaii. *J. natl Cancer Inst.*, 58, 1577-1581
- ⁵Tokudome, S., Kono, S., Ikeda, M., Kuratsune, M. & Kumamaru, S. (1981) Cancer and other causes of death among leprosy patients. *J. natl Cancer Inst.*, 67, 285-289
- ⁶Brinton, L.A., Hoover, R., Jacobson, R.R. & Fraumeni, J.F., Jr (1984) Cancer mortality among patients with Hansen's disease. *J. natl Cancer Inst.*, 72, 109-114
- ⁷*IARC Monographs, Suppl. 6, 210-211, 1987*