

PHENAZOPYRIDINE HYDROCHLORIDE (Group 2B)

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

In one limited epidemiological study, no significant excess of any cancer was observed among 2214 patients who received phenazopyridine hydrochloride and were followed for a minimum of three years¹.

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

Oral administration of phenazopyridine hydrochloride increased the incidence of hepatocellular adenomas and carcinomas in female mice and induced tumours of the colon and rectum in rats¹.

C. Other relevant data

No data were available on the genetic and related effects of phenazopyridine hydrochloride in humans. It did not induce sex-linked recessive lethal mutations in *Drosophila* and was not mutagenic to bacteria².

References

¹IARC Monographs, 24, 175-184, 1980

²IARC Monographs, Suppl. 6, 451-452, 1987