A 6-Month Study on the Toxicity of High Doses of Policosanol Orally Administered to Sprague-Dawley Rats.


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Policosanol is a cholesterol-lowering drug purified from sugar cane. Previous toxicological studies have not demonstrated any policosanol-related toxicity, even with long-term oral administration at 500 mg/kg, a dose 1,724 times larger than the maximal therapeutic dose (20 mg/day) recommended to date. The present study was undertaken to investigate the oral toxicity of policosanol administered for 6 months in doses up to 5,000 mg/kg to Sprague-Dawley rats. Animals were randomly distributed in five groups (15 animals per dose per sex): a control and four groups given oral policosanol (50, 500, 2,500, or 5,000 mg/kg). Eight treated rats (6 males, 2 females) died during the study, five of them (4 males, 1 female) from among those receiving the highest dose (5,000 mg/kg). According to necropsy, all deaths were related to gavage manipulation of higher doses. Although the differences were not significant, body weight gain and food consumption in the groups receiving 2,500 or 5,000 mg/kg tended to be lower than in the control group. Nevertheless, no drug-related toxicity symptoms were detected. Analysis of blood biochemistry, hematology, organ weight ratios, and histopathological findings did not show significant differences compared with controls, nor any tendency with the dose. Therefore, the present study did not show any new evidence of oral toxicity of policosanol, and the findings observed were a consequence of long-term administration by gastric gavage of the highly concentrated suspensions needed to reach the higher doses. It is concluded that policosanol chronically administered by the oral route is safe and that no drug-related toxicity was demonstrated.

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