High-fat breakfast increases bioavailability of albendazole compared to light breakfast: single-dose study in healthy subjects

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Abstract

Background – Albendazole is a benzoimidazole carbamate drug with anthelmintic and antiprotozoal activity against intestinal and tissue parasites. It has been described that the administration with meals increases albendazole absorption. Objective – Our aim was to compare the systemic exposure in healthy volunteers of two albendazole formulations after a single oral dose under fed conditions and to evaluate the effect of breakfast composition on its bioavailability. Methods – 12 healthy volunteers were included in a crossover, open, randomized comparative bioavailability trial including two stages. Single oral doses of 400 mg albendazole were administered under fed conditions (a light breakfast in first stage and a high-fat breakfast in the second) separated by 7-day washout periods. Plasma albendazole and albendazole sulfoxide concentrations were measured by HPLC-MS/MS. Results – Albendazole absorption was clearly influenced by the meal composition. A high-fat breakfast increased albendazole and albendazole sulfoxide area under the concentration-time curve (AUC) and maximum concentration (Cmax) by double compared to a light breakfast. The bioavailability of the two formulations was very similar, although the sample size was not sufficient to demonstrate bioequivalence because the intra-individual variability of albendazole was approximately 60%. Conclusions – The higher albendazole and albendazole sulfoxide levels when administered with a high-fat meal could be of importance in clinical practice. Since albendazole labelling recommends its administration with meals, it is necessary to insist the patient to take it with a fatty meal so that the effectiveness of albendazole is not compromised.

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