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Effects of Food on the Pharmacokinetics of Niflumic acid following Oral Administration of Talniflumate

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Pharmacokinetics of niflumic acid has been investigated following an oral administration of talniflumate in fasting and non-fasting healthy volunteers. Eight volunteers were enrolled in a randomized, single oral dose, two-period, parallel pharmacokinetic study. Talniflumate (740 mg) was administered in a fasting and in a feed of low or high fat meal with one-week washout period. Blood samples were serially collected up to 12 hrs. Plasma concentrations of niflumic acid and talniflumate were measured using LC-MS/MS. Systemic exposure of niflumic acid was significantly affected by food intake, but there were no notable differences between high- and low-fat diets. After the meal AUC_{inf} and C_{max} of niflumic acid increased by 4.0~4.6 (p<0.05) and 4.2~4.9 fold (p<0.1), respectively. In contrast to the report previously published by a group, talniflumate was not detected in plasma, even at 0.2 ng/ml of the low limit of quantification. Although it is not easy to clarify whether food affects the metabolism and/or absorption of talniflumate because of no information about the kinetic profiles of talniflumate, the clinical significance should be taken into account. Further investigation is still in progress.