This is provisional English translation of an excerpt from the original full report.

Risk Assessment Report

Dinital, an injectable agent for pigs which contains ketoprofen as an active ingredient

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of Dinital, an injectable agent for pigs which contains ketoprofen as an active ingredient, based on documents including a written application for marketing approval of a new veterinary medicinal product

Ketoprofen, the active ingredient of this veterinary medicinal product, is currently used within and outside Japan as a human medicinal product and a veterinary medicinal product, and its acceptable daily intake (ADI) has been specified as 0.001 mg/kg bw/day in Japan.

Regarding the additives used in Dinital, FSCJ concludes that considering the usage, existing data on toxicity and dosage regimen of Dinital, the risk to human health from the intake of these additives as ingredient of this product is negligible. In residue studies with administration of clinical doses of this product, residue leves of ketoprofen and metabolite A decreased with time to a level below the detection limit in the muscle two days after the injection in all cases. Residue levels of the metabolite A in other tissues decreased to a level below the detection limit 7 days after the injection, while a low level residue of ketoprofen was detected in a level close to the detection limit in the liver, kidney and small intestine 7 days after the injection. The level of these residues decreased with time afterwards.

There were no treatment-related changes caused by administration of this product in the safety and clinicalstudies. Hence, FSCJ concluded that the risk to human health from the intake of this product through consumption of foods is negligible as long as it is appropriately used.