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

Risk Assessment Report

PRONAMID Powder 1%

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)

October 2014

ABSTRACT

FSCJ conducted a risk assessment of PRONAMID Powder 1%, which contains mosapride citrate as an active component and administrated orally to horses, based on documents including a written application for marketing approval of a new veterinary medicinal product.

Mosapride citrate hydrate, the active ingredient of this veterinary medicinal product, is used as a human medicinal product. FSCJ conducted a risk assessment for specifying an acceptable daily intake (ADI) of mosapride as described in the Risk Assessment Report of mosapride (FS/790/2014), and specified the ADI of 0.03 mg/kg body weight/day as mosapride citrate hydrate.

Regarding the additives used in PRONAMID Powder 1%, FSCJ concluded that the risk to human health from the intake of these additives as ingredients of this product is negligible, considering the usage, existing data on toxicity evaluation, dosage and administration.

Mosapride citrate hydrate was detected only in the liver 5 days after the last administration in the residue test with the clinical dose. Its metabolite, M-1, was under the detection limit in all cases examined 3 days after the last administration.
Abnormal clinical symptoms or side effects caused by the administration of this product were not observed in safety and clinical studies in horses.

Consequently, FSCJ concludes that the risk to human health through consumption of foods containing PRONAMID Powder 1% is negligible as long as this product is appropriately used.