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

Risk Assessment Report

Zuprevo 40 injection

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
November 2019

ABSTRACT

FSCJ conducted a risk assessment of an injection for veterinary use in pigs, zuprevo 40 injection containing tildipirosin (PMT) as an active substance, using a written application for the approval of manufacture and sales of new veterinary medicinal products.

Previously, FSCJ has specified the ADI for the main component of this product, PMT, to be 0.03 mg/kg bw/day as is described in the attached “Risk Assessment Report on Tildipirosin”.
Regarding the additives used in this product, FSCJ concludes that the risk to human health from the use of these additives as a component of this product into target animals is negligible considering the usage, existing evaluation, and the dosage and administration.

Residue data indicated that the highest concentration of residual PMT among tissues after 32 days was 0.736 µg/g detected in the kidney that was one-twelfth of the residue at 4 days after the administration. The residue of PMT was detected also in the muscle at the administration site, its around area and the liver for rather long period after the administration. Therefore, FSCJ considers that setting an appropriate wash out period is necessary.

In safety studies and clinical studies with pigs, FSCJ recognized no particular issue as the effects of the administration of this product. Hence, FSCJ concluded that risk of this product to human through foods is negligible as long as it is appropriately used.

Due to a macrolide antimicrobial property of PMT, it is necessary for use of this product to consider the risk assessment of macrolide-resistant bacteria.