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

Risk Assessment Report

Zactran
(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
July 2014

ABSTRACT

FSCJ conducted a risk assessment of Zactron, an injection for cattle, which contains gamithromycin as an active ingredient based on a written application for the marketing approval of new veterinary medicinal products and its attached documents.

Gamithromycin, main ingredient of this product, is currently used as a veterinary medicinal product. FSCJ recently conducted an assessment of gamithromycin to specify the ADI as was reported[1], and estimated the ADI for gamithromysin as 0.01 mg/kg bw/day.

Regarding the additives used in this product, FSCJ concludes that considering the usage, existing toxicity evaluation, dosage and administration, the risk to human health from the intake of these additives as ingredient of this product can be negligible.

In feeding studies with administration of regular dose of this product, residues of gamithromycin decreased with time to ppb level in the tissues including the muscle of the injection site 65 days after the injection. No clinical issue was observed in the changes caused by administration of this product in the safety studies, suggesting that this product has no safety issue. In clinical studies, no abnormality of clinical manifestation and side effects due to the administration were observed.

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.
In use of this product, special attention needs to be paid for the risk from macrolide-resistant bacteria since gamithromycin is a macrolide antimicrobial agent.

[1] In the Risk Asessment Report, veterinary medicinal products FS/559/2014, Food Safety Commission of Japan.