

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

Risk Assessment Report

Zactran Merial

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
February 2017

ABSTRACT

Zactran Merial is an injection for pigs which contains gamithromycin, a family of antibiotic agents of macroride, as an active ingredient. FSCJ conducted a risk assessment of Zactran Merial based on documents submitted by the applicants for a new veterinary medicinal product.

Gamithromycin, main ingredient of this product, has been already specified the ADI of 0.01 mg/kg bw/day by FSCJ.

Regarding the additives used in this product, FSCJ concluded that the risk to human health from the intake of these additives as ingredients of this product is negligible when consider the usage, toxicological profiles, and the dosage and administration.

In residue analyses, concentrations of gamithromycin in tissues decreased with time, and were below the detection limit (50 ng/g) by 15 days after the injection except the muscle of the injection site and muscle near by.

In safety studies as well as in clinical studies, no sign of concern due to the injection of this product was observed.

Hence, FSCJ concluded that risk to human health from the product through dietary consumption is negligible as long as it is appropriately used.

When treated with this product, the risk from macrolide-resistant bacteria should be taken into consideration since gamithromycin is a macrolide antimicrobial agent.