

[P-67]

**Fertility Study of DA-8159, a New Medication against
Erectile Dysfunction, in Rats**

Moon Koo Chung¹, Jong Choon Kim², Jeong Eun Suh¹ and Sang Seop Han¹

¹Korea Institute of Toxicology, P.O. Box 107, Daejeon

²College of Veterinary Medicine, Chonnam National University, Gwangju

DA-8159, a new pyrazolopyrimidinone derivative for erectile dysfunction, was administered by gavage at levels of 0, 17.5, 70, and 280 mg/kg to Sprague-Dawley male rats from 28 days before mating to the end of mating period, and to females from 14 days before mating to day 6 of gestation. Effects of the test agent on general findings and reproductive performance of parent animals and on early embryonic development were examined. At 280mg/kg, salivation and hair loss were observed at a high incidence in males and females, respectively. One female out of twenty-four died during the treatment period. A decrease in food consumption and a decrease in body weight were observed in both sexes. No treatment-related gross findings and histoathological findings were seen, except that dead animal exhibited atrophy of the thymus. A decrease of prostate weight and an increase of liver, lung and spleen weights were seen. An increase in the period and irregularity of sexual cycle was observed. A decrease in fertility and pregnancy index was also seen. A decrease in the number of corpora lutea, implantations, and litter size was observed. There were no treatment-related changes in precoital time, mating index, sperm parameters, and serum testosterone concentration. At 17.5 mg/kg and 70 mg/kg, there were no adverse effects on all the parameters examined. Based on these results, DA-8159 induces body weight reduction, decreased food consumption, irregularity in sexual cycle, reduced fertility, and decreased number of corpora lutea, implantations, and litter size at 280 mg/kg and no observed adverse effect levels (NOAELs) of DA-8159 are considered to be 70 mg/kg for general toxicity and reproductive capability of parent animals and for early embryonic development, respectively.

Keyword : DA-8159, medication against erectile dysfunction, fertility study, rat