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Safety Evaluation of Nimesulide Injection

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***SUMMARY*. The aim of this study was to evaluate the pharmaceutical safety of Nimesulide Injection (NI). The median lethal dose (LD_{50}), accumulative toxicity and tolerance, muscle irritation and hemolysis of NI were determined by modified Karber's method, dose progressive increase method and routine method. In addition, long-term toxicity test of NI was carried out by intramuscular injection on Sprague Dawley (SD) rats for 60 days. The LD_{50} of NI was 183.5 mg/kg. The accumulative coefficient (*K*) was more than 5.28. Furthermore, there were no statistically significant differences ($P > 0.05$) between the test group and the control group in tolerance test. Moreover, no obvious hemolysis and muscle irritation were found in New Zealand rabbits after receiving NI. In addition, the blood parameters and organ index had no statistical significant differences ($P>0.05$) between the test group and the control group in long-term toxicity test on rats. Results suggested that NI has a relatively high security and can provide scientific basis for clinical trials and registration as a novel injectable pharmaceutical form in China.**

KEY WORDS: Injection, Nimesulide, Safety evaluation.

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