Abstract

The results of this study demonstrate that DLX 300 mg and 900 mg are safe and well tolerated in healthy subjects and have comparable pharmacokinetic profiles to those seen in a previous study (1). In addition, the results confirmed that DLX is well tolerated in healthy subjects at supratherapeutic concentrations.

Methods

Subjects were randomly assigned to receive single oral doses of DLX 300 mg (N = 26), 900 mg (N = 26), or placebo (N = 26). The study was conducted as an open-label, randomized, single-dose, 3-way crossover design with a 14-day washout period between each treatment. Blood samples were collected over 24 hours post-dose for measurement of DLX plasma concentrations.

The primary endpoint was the time-averaged plasma concentration (Ct) and the maximum plasma concentration (Cmax) of DLX. Additional endpoints included the area under the plasma concentration-time curve (AUC) and the percentage of the time above the minimum inhibitory concentration (MIC) (T>MIC), which was determined using the time-interval to a percentage of the maximum concentration (T>MIC) method.

Results

The pharmacokinetic parameters for DLX 300 mg and 900 mg are summarized in Table 1. The average Cmax and AUC were similar for both doses, indicating that the bioavailability of DLX is comparable across the dose range studied. The percentage of the time above the MIC (T>MIC) was also similar for both doses, indicating that the duration of effective concentrations is comparable.

Conclusions

In conclusion, the results of this study demonstrate that DLX 300 mg and 900 mg are safe and well tolerated in healthy subjects and have comparable pharmacokinetic profiles to those seen in a previous study. The study also confirmed that DLX is well tolerated in healthy subjects at supratherapeutic concentrations.

References


