



INFECTIOUS DISEASES (BACTERIAL, FUNGAL, VIRAL, PARASITIC, INFESTATIONS)

OZENOXACIN SAFETY PROFILE IN PEDIATRIC POPULATION WITH IMPETIGO

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Background: Ozenoxacin is a non-fluorinated quinolone that has been recently approved in 12 EU countries indicated for the short term treatment of non-bullous impetigo in adults, adolescents, children, and infants aged 6 months and older.

Objective: To get a clear awareness of the safety and effectiveness of ozenoxacin 1% topical cream in the pediatric ozenoxacin treated impetigo population participating in one Phase I-II and two Phase III clinical trials by age range and impetigo type.

Methods: The ozenoxacin treated pediatric population with non-bullous impetigo from 6 months to 18 years was re-analysed divided in 4 subgroups by age range (6m-<2y; 2-<6y; 6-<12y and 12-<18y). The treatment schedule was ozenoxacin 1% topical cream b.i.d. for 5 days in all three studies. Analysis of demographic parameters, baseline characteristics, clinical and microbiological outcomes and safety evaluation by subgroup was performed.

Results: 239 pediatric ozenoxacin treated patients were included in the 4 subgroups of this re-analysis. [(6m-<2y; n= 17 (7.1%)); (2-<6y; n=83 (34.7%)); (6-<12y; n=94 (39.3%) and 12-<18y; n=45 (18.82%)]. The demographic characteristics, the proportion of non-bullous impetigo patients and the clinical evaluation at baseline was very similar among the subgroups. The clinical success at end of therapy (day 6) was similar among subgroups, ranging from 88% to 100%. The microbiological eradication rate was also similar among subgroups, ranging from 82.6% to 100%. No ozenoxacin related adverse events were reported. There was availability of PK parameters in only 38 patients. Among the 327 plasma sample taken, only 1 sample from 1 patient in subgroup from 2-6y had detectable plasmatic concentrations very close to the LoQ. (0.5ng/mL)

Conclusion: Ozenoxacin has shown to be a safe and effective treatment for non-bullous impetigo in all pediatric age subgroups ranging from 6 months to 18 years old.

