Safety, tolerability and pharmacokinetics of intravaginal pentamycin

JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

ID 1193529
Author(s) Frey Tirri, B.; Bitzer, J.; Geudelin, B.; Drewe, J.
Author(s) at UniBasel Bitzer, Johannes ; Drewe, Jürgen ;
Year 2010
Title Safety, tolerability and pharmacokinetics of intravaginal pentamycin
Journal Chemotherapy
Volume 56
Number 3
Pages / **Article-Number** 190-6
BACKGROUND/AIMS: Intravaginal pentamycin is a polyene macrolide with a broad spectrum of antimicrobial activity and is effective in various forms of infectious vaginitis. We evaluated the safety, tolerability and pharmacokinetics of escalating doses of this product. METHODS: Nineteen healthy volunteers were randomized to receive double blind one of five doses of intravaginal pentamycin (3, 10, 30, 60 or 100 mg) or the corresponding dose of pentamycin vehicle daily for 6 days. Patients with symptomatic vaginitis received a single dose of 60 (n = 6) or 100 mg (n = 6) of intravaginal pentamycin. Safety and tolerability parameters were monitored throughout the study. Plasma concentrations of pentamycin were measured daily in the healthy volunteers and on the day of drug application in the patients. RESULTS: The most frequently reported adverse events were mild or moderate vaginal discharge and mild symptoms of vaginal irritation (mainly pruritus or burning sensation), which also occurred in women who applied the vehicle. No patient with symptomatic vaginitis reported treatment-related adverse events. The plasma levels of pentamycin were below the quantification limit in all samples. CONCLUSION: Intravaginal pentamycin does not cause adverse reactions compared with vehicle and is not absorbed through the intact or the inflamed vagina.
Publisher Karger
ISSN/ISBN 0009-3157 ; 1421-9794
edoc-URL http://edoc.unibas.ch/dok/A5840268
Full Text on edoc Available;
Digital Object Identifier DOI 10.1159/000316329
PubMed ID http://www.ncbi.nlm.nih.gov/pubmed/20551634
ISI-Number WOS:000278957700004
Document type (ISI) Journal Article, Randomized Controlled Trial