Annex IV

Conditions to the marketing authorisations for Fosfomycin calcium and Fosfomycin trometamol medicinal products

Conditions to the marketing authorisations

The marketing authorisation holders for medicinal products containing Fosfomycin calcium shall complete the below conditions, within the stated timeframe, and competent authorities shall ensure that the following is fulfilled:

In order to further characterise the pharmacokinetic profile and to confirm the efficacy of Fosfomycin calcium in the treatment of uncomplicated urinary tract infections in adult women the MAH(s) should conduct and submit the results of:	
• A pharmacokinetic study including population pharmacokinetic and pharmacokinetic-pharmacodynamic analyses to further characterise the dosage regimen.	
The complete study protocols should be submitted to the relevant National Competent Authorities for agreement:	Within 1 month after Commission decision
The final study report should be submitted to the relevant National Competent Authorities:	Within 16 months after Commission decision
• A non-inferiority clinical trial to evaluate the efficacy in the indication of uncomplicated urinary tract infections in adult women.	
The complete study protocols should be submitted to the relevant National Competent Authorities for agreement:	Within 18 months after Commission decision
The final study report should be submitted to the relevant National Competent Authorities:	Within 30 months after Commission decision

The marketing authorisation holders for medicinal products containing fosfomycin trometamol for the indication 'Perioperative antibiotic prophylaxis for transrectal prostate biopsy' shall complete the below conditions, within the stated timeframe, and competent authorities shall ensure that the following is fulfilled:

In order to support the two-dose posology in the indication 'Perioperative antibiotic prophylaxis for transrectal prostate biopsy' the MAH(s) should conduct and submit the results of a phase I study in healthy volunteers including pharmacokinetic -pharmacodynamic analyses.	
The complete study protocols should be submitted to the relevant National Competent Authorities for agreement:	Within 1 month after Commission decision
The final study report should be submitted to the relevant National Competent Authorities:	Within 16 months after Commission decision