

Supplementary Table 4. Serious adverse drug reactions

Variable	Safety analysis set (<i>n</i> =3,231)	
	No. of patients (%)	No. of events
Total (sAE)	55 (1.70)	67
Total (sADR)	5 (0.15)	5
Pylonephritis acute	1 (0.03)	1
Ureterolithiasis	1 (0.03)	1
Cervix inflammation	1 (0.03)	1
Hyperglycemia	1 (0.03)	1
Hyponatremia	1 (0.03)	1

sAE, serious adverse event; sADR, serious adverse drug reaction.