

Overall incidence of urinary tract infections (UTI) AEs ¹

The overall population* incidence of UTI AEs was slightly higher with canagliflozin compared with placebo.

The majority of subjects with UTI AEs were women (87.1%). Of 111 subjects with UTI AEs, 68.5% had symptomatic UTIs – the most common symptoms reported were dysuria, frequency, urgency, and/or suprapubic pain.

Proportion of subjects treated with antimicrobial therapy tended to be higher in placebo group than canagliflozin 100mg and 300mg (84.6%, 75.5% and 80.6% respectively).

	Placebo n=646	Canagliflozin 100 mg n=833	Canagliflozin 300 mg n=834
	<i>Subjects, n (%)</i>		
Any UTI AE	26 (4.0)	49 (5.9)	36 (4.3)
AEs leading to discontinuation	1 (0.2)	1 (0.1)	0
AEs related to study drug*	10 (1.5)	25 (3.0)	21 (2.5)
Serious AEs	0	2 (0.2)	1 (0.1)
Symptomatic UTI	17 (2.6)	32 (3.8)	27 (3.2)
Upper UTI	0	1 (0.1)	1 (0.1)

*Possibly, probably, or very likely related to study drug, as assessed by investigators

*Subjects from 4 placebo-controlled, 26-week studies (CANA as monotherapy, add-on to metformin [MET], add-on to MET plus sulfonylurea, and add-on to MET plus pioglitazone)

Reference: 1. Meininger et al Poster presented at the 49th Annual Meeting of the European Association for the Study of Diabetes (EASD), 23-27th September 2013, Barcelona, Spain.

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