

Supplementary Table 1. Incidence of ADRs

	PMS (n=3,882)			
	Serious events		All events	
	%	No. of ADRs/ 100 pt-yrs	%	No. of ADRs/ 100 pt-yrs
ADRs	2.52	6.42	15.66	47.34
System Organ Classification				
Infections and infestations	1.03	2.39	5.87	14.10
Neoplasms benign, malignant and unspecified (including cysts and polyps)	0.15	0.32	0.15	0.32
Blood and lymphatic system disorders	0.08	0.16	0.15	0.32
Immune system disorders	0.08	0.16	0.15	0.32
Endocrine disorders	0	0	0.03	0.05
Metabolism and nutrition disorders	0.05	0.16	0.15	0.37
Psychiatric disorders	0	0	0.05	0.11
Nervous system disorders	0.13	0.32	1.03	2.81
Eye disorders	0.03	0.05	0.13	0.27
Ear and labyrinth disorders	0	0	0.05	0.11
Cardiac disorders	0.05	0.11	0.18	0.48
Vascular disorders	0.08	0.16	0.23	0.58
Respiratory, thoracic and mediastinal disorders	0.31	0.69	2.16	4.98
Gastrointestinal disorders	0.26	0.90	1.96	5.20
Hepatobiliary disorders	0.13	0.27	1.06	2.17
Skin and subcutaneous tissue disorders	0.10	0.21	2.19	5.88
Musculoskeletal, and connective tissue disorders	0.03	0.05	0.26	0.53
Renal and urinary disorders	0.05	0.11	0.10	0.21
Reproductive system and breast disorders	0	0	0.05	0.16
General disorders and administration site conditions	0	0	1.29	3.29
Investigations	0.10	0.21	1.65	4.77
Injury, poisoning and procedural complications	0.08	0.16	0.15	0.32

ADRs were reported in terms of system organ class using MedDRA version 15.0.

ADR, adverse drug reaction; PMS, postmarketing surveillance; pt, patient; yrs, years