

Variable	Adverse event		Adverse drug reaction	
	No. (%)	95% CI	No. (%)	95% CI
Total	492 (1.74)	1.58–1.89	123 (0.43)	0.36-0.51
Centr & periph nervous system disorders	103 (0.36)	0.29-0.43	13 (0.05)	0.02-0.07
Liver and biliary system disorders	99 (0.35)	0.28-0.42	46 (0.16)	0.12-0.21
Gastro-intestinal system disorders	94 (0.33)	0.26-0.40	13 (0.05)	0.02-0.07
Body as a whole: general disorders	79 (0.28)	0.22-0.34	4 (0.01)	0.00-0.03
Metabolic and nutritional disorders	68 (0.24)	0.18-0.30	32 (0.11)	0.07-0.15
Respiratory system disorders	64 (0.23)	0.17-0.28	2 (0.01)	0.00-0.02
Psychiatric disorders	51 (0.18)	0.13-0.23	3 (0.01)	0.00-0.02
Musculo-skeletal system disorders	50 (0.18)	0.13-0.23	10 (0.04)	0.01-0.06
Urinary system disorders	47 (0.17)	0.12-0.21	1 (0)	0.00-0.01
Cardiovascular disorders, general	27 (0.1)	0.06-0.13	1 (0)	0.00-0.01
Skin and appendages disorders	23 (0.08)	0.05-0.11	7 (0.02)	0.01-0.04
Vascular (extracardiac) disorders	11 (0.04)	0.02-0.06	1 (0)	0.00-0.01
Heart rate and rhythm disorders	8 (0.03)	0.01-0.05	1 (0)	0.00-0.01
Platelet, bleeding & clotting disorders	7 (0.2)	0.01-0.04	-	
Resistance mechanism disorders	7 (0.2)	0.01-0.04	-	
Vision disorders	7 (0.2)	0.01-0.04	-	
Myo-endo pericardial & valve disorders	6 (0.2)	0.00-0.04	-	
Red blood cell disorders	6 (0.2)	0.00-0.04	-	
Reproductive disorders, male	4 (0.1)	0.00-0.03	-	
Secondary terms	4 (0.1)	0.00-0.03	-	
Foetal disorders	3 (0.1)	0.00-0.02	-	
Neoplasm	3 (0.1)	0.00-0.02	-	
Application site disorders	2 (0.1)	0.00-0.02	-	
Hearing and vestibular disorders	2 (0.1)	0.00-0.02	-	
Collagen disorders	1 (0.00)	0.00-0.01	-	
Endocrine disorders	1 (0.00)	0.00-0.01	-	
Reproductive disorders, female	1 (0.00)	0.00-0.01	-	