

**Supplementary Table.** Number (%) of patients experiencing bleeding adverse events

presented by primary system organ class and preferred term and maximal intensity among the ITT population

Primary system organ class Preferred term	Clopidogrel					
	50mg (n=558)			75mg (n=552)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Any class	65 (11.6%)	11 (2.0%)	2 (0.4%)	80 (14.5%)	10 (1.8%)	2 (0.4%)
Injury, poisoning and procedural complications	10 (1.8%)	2 (0.4%)	0	21 (3.8%)	2 (0.4%)	0
Skin laceration	1 (0.2%)	0	0	7 (1.3%)	0	0
Contusion	4 (0.7%)	1 (0.2%)	0	2 (0.4%)	0	0
Excoriation	1 (0.2%)	0	0	2 (0.4%)	0	0
Limb injury	1 (0.2%)	0	0	1 (0.2%)	0	0
Subcutaneous haematoma	1 (0.2%)	0	0	1 (0.2%)	0	0
Face injury	0	0	0	0	1 (0.2%)	0
Foot fracture	0	0	0	1 (0.2%)	0	0
Injury	0	0	0	1 (0.2%)	0	0
Mouth injury	0	0	0	1 (0.2%)	0	0
Subdural haematoma	0	0	0	0	1 (0.2%)	0
Tendon rupture	0	0	0	1 (0.2%)	0	0
Tongue injury	0	0	0	1 (0.2%)	0	0
Traumatic haematoma	0	0	0	1 (0.2%)	0	0
Traumatic haemorrhage	0	0	0	1 (0.2%)	0	0
Wound	0	0	0	1 (0.2%)	0	0
Animal bite	2 (0.4%)	0	0	0	0	0
Bite	0	1 (0.2%)	0	0	0	0
Periorbital haematoma	1 (0.2%)	0	0	0	0	0
Gastrointestinal disorders	16 (2.9%)	2 (0.4%)	0	13 (2.4%)	3 (0.5%)	0
Gingival bleeding	2 (0.4%)	0	0	7 (1.3%)	0	0
Haemorrhoidal haemorrhage	3 (0.5%)	0	0	1 (0.2%)	1 (0.2%)	0
Haematochezia	2 (0.4%)	0	0	1 (0.2%)	0	0
Lip haemorrhage	1 (0.2%)	0	0	1 (0.2%)	0	0
Mouth haemorrhage	1 (0.2%)	0	0	1 (0.2%)	0	0
Duodenal ulcer haemorrhage	0	0	0	0	1 (0.2%)	0
Gastrointestinal haemorrhage	0	0	0	1 (0.2%)	0	0
Oesophageal haemorrhage	0	0	0	0	1 (0.2%)	0
Periodontitis	0	0	0	1 (0.2%)	0	0
Gastric ulcer haemorrhage	1 (0.2%)	2 (0.4%)	0	0	0	0
Melaena	2 (0.4%)	0	0	0	0	0
Faeces discoloured	1 (0.2%)	0	0	0	0	0
Gingivitis	1 (0.2%)	0	0	0	0	0
Haemorrhoids	1 (0.2%)	0	0	0	0	0
Tongue haematoma	1 (0.2%)	0	0	0	0	0
Tooth socket haemorrhage	1 (0.2%)	0	0	0	0	0

Primary system organ class	Clopidogrel					
	50mg (n=558)			75mg (n=552)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
<b>Respiratory, thoracic and mediastinal disorders</b>						
Preferred term						
Respiratory, thoracic and mediastinal disorders	12 (2.2%)	3 (0.5%)	0	13 (2.4%)	0	0
Epistaxis	12 (2.2%)	2 (0.4%)	0	13 (2.4%)	0	0
Nasal polyps	0	1 (0.2%)	0	0	0	0
<b>Skin and subcutaneous tissue disorders</b>						
Haemorrhage subcutaneous	9 (1.6%)	0	0	10 (1.8%)	0	0
Nail bed bleeding	0	0	0	1 (0.2%)	0	0
Rash	0	0	0	1 (0.2%)	0	0
Vascular purpura	0	0	0	1 (0.2%)	0	0
Purpura	2 (0.4%)	0	0	0	0	0
<b>Eye disorders</b>						
Conjunctival haemorrhage	5 (0.9%)	0	0	9 (1.6%)	0	0
Vitreous haemorrhage	1 (0.2%)	1 (0.2%)	0	1 (0.2%)	1 (0.2%)	0
Retinal haemorrhage	0	0	0	2 (0.4%)	0	0
Hyphaema	1 (0.2%)	0	0	0	0	0
Ocular hyperaemia	1 (0.2%)	0	0	0	0	0
Optic disc haemorrhage	1 (0.2%)	0	0	0	0	0
Retinal vein occlusion	0	1 (0.2%)	0	0	0	0
Retinopathy haemorrhagic	1 (0.2%)	0	0	0	0	0
<b>Investigations</b>						
Occult blood	0	0	0	3 (0.5%)	1 (0.2%)	0
Occult blood positive	1 (0.2%)	0	0	3 (0.5%)	0	0
Blood urine present	2 (0.4%)	0	0	1 (0.2%)	0	0
Bleeding time prolonged	1 (0.2%)	0	0	0	0	0
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>						
Colon cancer	1 (0.2%)	0	0	1 (0.2%)	0	1 (0.2%)
Bladder cancer	0	0	0	1 (0.2%)	0	0
Rectal cancer stage 0	0	0	0	0	0	1 (0.2%)
Gastric cancer	0	0	1 (0.2%)	0	0	0
Large intestine carcinoma	1 (0.2%)	0	0	0	0	0
Rectal cancer	0	0	1 (0.2%)	0	0	0
Uterine leiomyoma	0	1 (0.2%)	0	0	0	0
<b>Vascular disorders</b>						
Haemorrhage	1 (0.2%)	0	0	4 (0.7%)	0	0
Wound haemorrhage	1 (0.2%)	0	0	0	0	0
<b>Musculoskeletal and connective tissue disorders</b>						
Muscle haemorrhage	0	0	0	0	2 (0.4%)	0
Haemarthrosis	1 (0.2%)	0	0	1 (0.2%)	0	0

Primary system organ class	Clopidogrel					
	50mg (n=558)			75mg (n=552)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
<b>Renal and urinary disorders</b>	4 (0.7%)	0	0	1 (0.2%)	1 (0.2%)	0
Calculus ureteric	2 (0.4%)	0	0	0	1 (0.2%)	0
Haematuria	1 (0.2%)	0	0	1 (0.2%)	0	0
Nephrolithiasis	1 (0.2%)	0	0	0	0	0
<b>General disorders and administration site conditions</b>	1 (0.2%)	1 (0.2%)	0	1 (0.2%)	0	0
Vessel puncture site haemorrhage	0	0	0	1 (0.2%)	0	0
Puncture site haemorrhage	1 (0.2%)	1 (0.2%)	0	0	0	0
Vessel puncture site haematoma	1 (0.2%)	0	0	0	0	0
<b>Reproductive system and breast disorders</b>	2 (0.4%)	0	0	1 (0.2%)	0	0
Haematospermia	0	0	0	1 (0.2%)	0	0
Genital haemorrhage	2 (0.4%)	0	0	0	0	0
<b>Nervous system disorders</b>	0	1 (0.2%)	0	1 (0.2%)	0	0
Thalamus haemorrhage	0	0	0	1 (0.2%)	0	0
Cerebral haemorrhage	0	1 (0.2%)	0	0	0	0
<b>Blood and lymphatic system disorders</b>	0	0	0	1 (0.2%)	0	0
Haemorrhagic disorder	0	0	0	1 (0.2%)	0	0
<b>Ear and labyrinth disorders</b>	0	0	0	1 (0.2%)	0	0
Tympanic membrane perforation	0	0	0	1 (0.2%)	0	0
<b>Infections and infestations</b>	2 (0.4%)	0	0	0	0	0
Cystitis	1 (0.2%)	0	0	0	0	0
Urinary tract infection	1 (0.2%)	0	0	0	0	0

n (%) = number and percentage of patients with at least one adverse event

MedDRA version: 11.1

Note: In case of several occurrences for the same PT (respectively SOC), the maximal intensity is used.