

olanzapine to end January 2009

			Case Group	Death Outcomes	Sole	
Case Count			1331	42	889	
Medicine	Reaction Count	Blood and lymphatic system disorders	Anaemia	6	1	2
			Hypochromic anaemia	6	0	6
			Normochromic normocytic anaemia	1	0	0
			Aplastic anaemia	2	0	2
			Bone marrow failure	2	0	2
			Pancytopenia	5	0	3
			Thrombocythaemia	1	0	0
			Thrombocytopenia	10	0	4
			Splenomegaly	1	0	0
			Eosinophilia	4	0	3
			Leukocytosis	16	1	3
			Lymphocytosis	1	1	0
			Monocytosis	1	0	1
			Neutrophilia	2	0	2
			Eosinopenia	1	0	1
			Leukopenia	27	0	17
			Lymphopenia	3	0	2
			Agranulocytosis	7	0	2
			Febrile neutropenia	1	0	1
			Neutropenia	58	1	32
			Blood and lymphatic system disorders	155	4	83
		Cardiac disorders	Atrioventricular block	1	0	1
			Bundle branch block	1	0	0
			Arrhythmia	3	1	1
			Bradycardia	10	1	7
			Extrasystoles	3	0	2
			Tachycardia	19	0	12
			Atrial fibrillation	6	0	5
			Sinus arrest	1	0	0
			Sinus bradycardia	1	0	0
			Sinus tachycardia	1	0	0
			Supraventricular tachycardia	1	0	0
			Cardiac arrest	8	6	3
			Torsade de pointes	2	0	1
Ventricular fibrillation	1	1	1			
Ventricular tachycardia	3	0	2			
Cardiac disorder	2	0	1			
Cyanosis	1	0	1			
Palpitations	3	0	0			
Mitral valve incompetence	1	0	0			
Myocardial infarction	4	0	2			

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Cardiac disorders	Cardiac failure	6	0	2
			Cardiac failure congestive	1	0	1
			Cardiomyopathy	14	2	3
			Cardiomegaly	3	0	3
			Myocarditis	4	2	0
			Cardiac tamponade	1	0	1
			Pericardial effusion	3	0	1
			Cardiac disorders	104	13	50
		Congenital, familial and genetic disorders	Ebstein's anomaly	1	0	0
			Oesophageal atresia	1	0	1
			Cleft palate	1	0	0
			Cleft lip	1	0	1
			Congenital foot malformation	1	0	0
			Polydactyly	1	0	0
			Congenital brain damage	1	0	1
			Congenital hydrocephalus	1	0	1
			Renal aplasia	1	0	0
			Tracheo-oesophageal fistula	1	0	1
			Congenital, familial and genetic disorders	10	0	5
			Ear and labyrinth disorders	Hyperacusis	1	0
		Tinnitus		3	0	1
		Vertigo		2	0	1
		Ear and labyrinth disorders		6	0	3
		Endocrine disorders	Cushing's syndrome	2	0	1
			Hyperprolactinaemia	10	0	9
			Inappropriate antidiuretic hormone secretion	1	0	1
			Endocrine disorders	13	0	11
		Eye disorders	Cataract	2	0	1
			Eye disorder	1	0	1
			Eye pain	1	0	0
			Conjunctivitis	4	0	3
			Blepharitis	1	0	1
			Blepharospasm	1	0	1
			Oculogyric crisis	4	0	3
			Miosis	4	0	3
			Mydriasis	1	0	1
			Photophobia	2	0	1
			Retinal degeneration	1	0	0
			Visual acuity reduced	1	0	1
			Chromatopsia	1	0	1
		Eye disorders	5	0	4	

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole		
		Eye disorders	Visual impairment	8	0	6	
			Optic neuropathy	1	0	1	
			Eye disorders	38	0	28	
		Gastrointestinal disorders	Pancreatitis	7	0	3	
			Pancreatitis acute	2	0	1	
			Pancreatitis necrotising	1	0	1	
			Rectal haemorrhage	1	0	0	
			Gastrointestinal haemorrhage	2	0	2	
			Haematemesis	1	0	0	
			Diarrhoea	8	0	5	
			Colonic pseudo-obstruction	1	0	1	
			Constipation	8	0	5	
			Dyspepsia	2	0	0	
			Eructation	2	0	1	
			Abdominal distension	6	0	4	
			Flatulence	6	0	5	
			Abdominal pain	5	0	2	
			Abdominal pain upper	1	0	1	
			Dysphagia	5	1	3	
			Nausea	18	0	10	
			Vomiting	20	0	14	
			Obstruction gastric	1	0	1	
			Ileus	1	0	1	
			Gastric ulcer	1	0	0	
			Mouth ulceration	4	0	3	
			Ascites	1	0	1	
			Dry mouth	8	0	5	
			Salivary hypersecretion	14	0	5	
			Salivary gland enlargement	1	0	0	
			Swollen tongue	1	0	0	
			Tongue discolouration	1	0	1	
			Tongue oedema	5	0	3	
			Gastrointestinal disorders	134	1	78	
			General disorders and administration site conditions	Hyperthermia malignant	1	0	0
				Hypothermia	10	0	8
				Pyrexia	62	2	29
		Death		6	6	3	
		Death neonatal		1	0	0	
		Sudden death		9	9	3	
		Asthenia		3	0	3	
		Fatigue		13	0	6	
Malaise	10	0		7			

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		General disorders and administration site conditions	Sluggishness	1	0	1
			Gait disturbance	10	1	6
			Condition aggravated	3	0	2
			Disease progression	1	0	1
			Disease recurrence	1	0	1
			Foaming at mouth	1	0	0
			Influenza like illness	7	0	5
			Pseudocyst	1	0	1
			Swelling	1	0	0
			Polyserositis	1	0	1
			Face oedema	19	0	17
			Generalised oedema	7	0	6
			Gravitational oedema	17	0	16
			Oedema	17	0	13
			Oedema peripheral	48	0	43
			Chest pain	9	0	5
			Discomfort	1	0	1
			Pain	8	0	8
			Chills	12	0	6
			Feeling jittery	1	0	0
			Hunger	1	0	0
			Thirst	5	0	4
			Drug interaction	3	0	0
			Drug effect decreased	1	0	1
			Drug ineffective	18	2	10
			Paradoxical drug reaction	1	0	1
			Therapeutic response decreased	2	0	1
			Drug withdrawal syndrome	2	0	1
			Drug withdrawal syndrome neonatal	2	0	0
			Fat necrosis	1	0	0
			General disorders and administration site conditions	317	20	210
		Hepatobiliary disorders	Cholecystitis	1	0	0
			Hyperbilirubinaemia	3	0	1
			Jaundice	7	0	5
			Jaundice cholestatic	1	0	0
			Hepatic function abnormal	56	1	32
			Hepatomegaly	2	0	0
			Hepatosplenomegaly neonatal	1	0	0
			Autoimmune hepatitis	1	0	0
			Hepatic steatosis	3	1	1
			Hepatitis	7	0	1
			Hepatitis fulminant	1	0	0

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			Case Group	Death Outcomes	Sole		
Medicine	Reaction Count	Hepatobiliary disorders	Hepatocellular injury	2	0	1	
			Hepatobiliary disorders	85	2	41	
		Immune system disorders	Hypersensitivity	2	0	0	
			Immune system disorders	2	0	0	
		Infections and infestations	Cellulitis	1	0	0	
			Eye infection	1	0	1	
			Vaginal infection	1	0	1	
			Infection	1	0	1	
			Bronchitis	1	0	1	
			Pneumonia	7	2	4	
			Bacteraemia	1	0	1	
			Sepsis	2	0	1	
			Rash pustular	2	0	1	
			Pharyngitis	1	0	0	
			Rhinitis	1	0	1	
			Urinary tract infection	1	0	0	
			Infections and infestations	20	2	12	
			Injury, poisoning and procedural complications	Drug toxicity	4	3	3
				Drug exposure during pregnancy	8	0	3
		Subdural haematoma		1	0	0	
		Fall		3	0	0	
		Incorrect dose administered		1	0	1	
		Intentional overdose		4	0	2	
		Overdose		13	3	9	
		Injury, poisoning and procedural complications		34	6	18	
		Investigations	Cardiac murmur	2	0	2	
			Ejection fraction decreased	1	0	0	
			Electrocardiogram QT prolonged	9	0	9	
			Electrocardiogram T wave inversion	1	0	0	
			Electrocardiogram abnormal	5	0	3	
			Heart rate decreased	1	0	1	
			Heart rate increased	1	0	1	
			Heart rate irregular	1	0	1	
			Blood pressure increased	1	0	0	
			Blood prolactin increased	3	0	1	
			Blood testosterone increased	1	0	1	
			Blood creatine phosphokinase increased	53	2	27	
			Cardiac enzymes increased	1	0	0	
			Troponin increased	3	1	0	
			Blood alkaline phosphatase increased	6	0	4	
			Blood lactate dehydrogenase increased	2	0	2	

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Medicine	Reaction Count	Investigations	Case Group	Death Outcomes	Sole
		Blood amylase increased	1	0	1
		Lipase increased	1	0	0
		Prothrombin level increased	1	1	0
		Red blood cell sedimentation rate increased	2	0	1
		Platelet count decreased	1	0	0
		Lymphocyte count decreased	1	0	0
		Neutrophil count decreased	3	0	3
		White blood cell count decreased	2	0	0
		White blood cell count increased	1	0	0
		Alanine aminotransferase increased	10	0	5
		Ammonia increased	1	0	0
		Aspartate aminotransferase increased	5	0	2
		Blood bilirubin increased	1	0	1
		Gamma-glutamyltransferase increased	8	0	7
		Hepatic enzyme increased	1	0	1
		Liver function test abnormal	15	0	6
		Antinuclear antibody positive	1	0	1
		Immunoglobulins increased	1	0	1
		Blood cholesterol increased	4	0	2
		Blood triglycerides increased	3	0	2
		Blood glucose fluctuation	1	0	1
		Blood glucose increased	6	0	5
		Electroencephalogram abnormal	1	0	1
		Apgar score abnormal	1	0	1
		Body temperature decreased	1	0	0
		Body temperature increased	2	0	0
		Weight decreased	4	0	2
		Weight increased	97	1	85
		C-reactive protein increased	3	0	2
		Creatinine renal clearance decreased	1	0	0
		Drug level above therapeutic	2	1	1
		Drug level changed	1	0	0
		Drug level increased	6	1	2
		Blood phosphorus decreased	1	0	0
		Investigations	281	7	185
		Metabolism and nutrition disorders			
		Ketoacidosis	4	0	3
		Acidosis	1	0	1
		Anorexia	3	0	1
		Food craving	1	0	1
		Increased appetite	16	0	15
		Obesity	3	0	2
		Hypercalcaemia	4	1	3

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Metabolism and nutrition disorders	Hypocalcaemia	1	1	0
			Diabetic ketoacidosis	3	0	2
			Hyperglycaemic hyperosmolar nonketotic syndrome	1	0	1
			Polydipsia	8	1	6
			Hyperkalaemia	2	0	2
			Hypokalaemia	3	1	1
			Hypernatraemia	1	0	0
			Hyponatraemia	14	2	8
			Dehydration	2	0	1
			Diabetes mellitus	28	0	26
			Type 1 diabetes mellitus	3	0	3
			Type 2 diabetes mellitus	6	0	6
			Glucose tolerance impaired	3	0	2
			Hyperglycaemia	17	0	14
			Hypoglycaemia neonatal	1	0	0
			Hypertriglyceridaemia	1	0	1
			Hyperlipidaemia	1	0	0
			Hyperammonaemia	1	0	0
			Hyperproteinaemia	1	0	1
			Hypoproteinaemia	3	0	2
		Metabolism and nutrition disorders	132	6	102	
		Musculoskeletal and connective tissue disorders	Jaw disorder	1	0	1
			Arthritis	1	0	1
			Arthralgia	10	0	9
			Joint stiffness	1	0	0
			Joint swelling	2	0	2
			Osteoarthritis	4	0	4
			Myalgia	16	0	11
			Muscle spasms	3	0	3
			Muscle twitching	20	0	15
			Hypertonia neonatal	1	0	0
			Muscle rigidity	5	0	2
			Nuchal rigidity	1	0	1
			Muscular weakness	1	0	0
Rhabdomyolysis	7		0	1		
Mastication disorder	1	0	0			
Mobility decreased	1	0	0			
Musculoskeletal stiffness	8	0	1			
Back pain	1	0	1			
Pain in extremity	2	0	2			
Musculoskeletal and connective tissue disorders	86	0	54			

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer female	2	0	2
			Pituitary tumour	1	0	1
			Prolactinoma	1	0	1
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	0	4
		Nervous system disorders	Cerebral haemorrhage neonatal	1	0	0
			Cerebrovascular accident	4	1	4
			Haemorrhagic stroke	1	1	1
			Cerebrovascular disorder	1	0	1
			Transient ischaemic attack	2	0	1
			Cranial nerve disorder	1	0	1
			Facial palsy	1	0	1
			Hypoxic encephalopathy	1	0	1
			Headache	19	0	12
			Dementia	1	0	1
			Amnesia	7	0	2
			Memory impairment	1	0	0
			Cognitive disorder	4	0	1
			Disturbance in attention	4	0	2
			Choreoathetosis	3	0	2
			Akathisia	25	1	4
			Bradykinesia	2	0	0
			Dyskinesia	14	0	12
			Extrapyramidal disorder	30	1	22
			Hyperkinesia	16	0	11
			Hypokinesia	4	1	4
			Tardive dyskinesia	22	1	14
			Dystonia	26	1	18
			Opisthotonus	4	0	2
			Hemiparesis	1	0	1
			Paralysis	2	0	2
			Paresis	1	0	0
			Cogwheel rigidity	2	0	0
			Parkinsonian gait	2	0	0
			Parkinsonism	7	0	7
			Asterixis	1	0	0
			Tremor	45	1	24
			Tremor neonatal	1	0	0
			Cerebral cyst	1	0	1
			Hyperreflexia	5	0	1
			Ataxia	12	1	6
			Coordination abnormal	1	0	0
			Nystagmus	1	0	0

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Nervous system disorders	Coma	8	1	5
			Diabetic coma	2	0	2
			Aphasia	2	0	1
			Dysgraphia	1	0	1
			Dyspraxia	1	0	1
			Altered state of consciousness	4	0	1
			Consciousness fluctuating	4	0	2
			Depressed level of consciousness	6	1	3
			Loss of consciousness	5	0	2
			Sedation	6	1	1
			Somnolence	48	0	32
			Somnolence neonatal	1	0	1
			Syncope	14	0	5
			Clonus	1	0	0
			Dizziness	19	1	12
			Drooling	2	0	1
			Myoclonus	3	0	1
			Unresponsive to stimuli	3	0	1
			Burning sensation	1	0	1
			Formication	1	0	1
			Paraesthesia	4	0	3
			Hypoaesthesia	3	0	3
			Dysarthria	6	0	6
			Incoherent	1	0	0
			Speech disorder	10	0	8
			Visual field defect	1	0	1
			Cholinergic syndrome	1	0	0
			Hypertonia	45	3	20
			Neuroleptic malignant syndrome	59	3	23
			Serotonin syndrome	10	0	1
			Muscle contractions involuntary	1	0	1
			Carpal tunnel syndrome	1	0	1
			Neuropathy peripheral	2	0	1
			Petit mal epilepsy	1	0	0
			Convulsion neonatal	2	0	0
			Grand mal convulsion	13	0	8
			Convulsion	49	2	27
			Frontal lobe epilepsy	1	0	1
			Hypersomnia	1	0	1
			Nervous system disorders	619	21	338
			Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	2	0
Intra-uterine death	1	0		0		

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			Case Group	Death Outcomes	Sole	
Medicine	Reaction Count	Pregnancy, puerperium and perinatal conditions	Foetal distress syndrome	1	0	0
			Foetal growth retardation	1	0	0
			Antepartum haemorrhage	1	0	1
			Premature separation of placenta	1	0	1
			Pre-eclampsia	1	0	1
			Small for dates baby	1	0	0
			Weight decrease neonatal	1	0	0
			Jaundice neonatal	1	0	1
			Neonatal disorder	1	0	1
			Oligohydramnios	1	0	0
			Pregnancy, puerperium and perinatal conditions	13	0	5
		Psychiatric disorders	Agitation	38	0	18
			Agitation neonatal	2	0	1
			Anxiety	12	0	6
			Nervousness	7	0	2
			Fear	1	0	0
			Panic attack	1	0	0
			Neurosis	8	0	4
			Obsessive-compulsive disorder	2	0	2
			Catatonia	10	1	5
			Restlessness	6	0	1
			Bruxism	1	0	1
			Stereotypy	1	0	0
			Dysphemia	1	0	0
			Screaming	1	0	0
			Confusional state	45	2	24
			Disorientation	4	0	2
			Delirium	23	0	10
			Depression	11	0	6
			Depression suicidal	1	0	1
			Depressed mood	3	0	2
			Depersonalisation	3	0	3
			Delusion	5	0	3
			Persecutory delusion	1	0	0
			Hallucination	25	1	13
			Hallucination, auditory	1	0	0
Hallucination, visual	1	0	1			
Thinking abnormal	10	1	8			
Impulsive behaviour	1	0	0			
Hypomania	1	0	0			
Mania	12	0	6			
Affect lability	1	0	1			

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Psychiatric disorders	Flat affect	1	0	1
			Dysphoria	1	0	1
			Euphoric mood	3	0	2
			Apathy	3	0	1
			Aggression	30	2	9
			Homicidal ideation	10	1	1
			Paranoia	3	0	0
			Social avoidant behaviour	1	0	1
			Personality disorder	8	0	7
			Abnormal behaviour	1	0	1
			Alcohol abuse	1	0	1
			Drug dependence	1	0	1
			Intentional drug misuse	1	0	0
			Withdrawal syndrome	13	1	8
			Psychotic disorder	17	1	10
			Schizophreniform disorder	2	0	2
			Schizophrenia	1	0	1
			Orgasmic sensation decreased	1	0	1
			Libido decreased	1	0	1
			Insomnia	13	0	9
			Abnormal sleep-related event	1	0	0
			Nightmare	4	0	2
			Somnambulism	1	0	1
			Sleep disorder	2	0	2
			Completed suicide	4	4	2
			Intentional self-injury	5	0	2
			Self injurious behaviour	2	0	1
			Suicidal behaviour	2	0	0
			Suicidal ideation	31	1	5
			Suicide attempt	37	3	7
			Psychiatric disorders	440	18	200
		Renal and urinary disorders	Nephrotic syndrome	2	0	1
			Tubulointerstitial nephritis	2	0	2
			Anuria	1	0	0
			Renal failure	1	0	1
			Renal failure acute	4	1	2
			Renal impairment	5	0	2
			Enuresis	1	0	0
			Incontinence	2	1	2
			Pollakiuria	1	0	1
			Urinary hesitation	1	0	0
			Urinary incontinence	15	0	9

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole		
		Renal and urinary disorders	Urinary retention	11	0	8	
			Albuminuria	3	0	2	
			Haematuria	2	0	2	
			Nocturia	1	0	1	
			Polyuria	9	0	7	
			Renal and urinary disorders	61	2	40	
		Reproductive system and breast disorders	Breast enlargement	3	0	2	
			Breast mass	2	0	1	
			Gynaecomastia	14	0	11	
			Breast pain	3	0	2	
			Nipple pain	1	0	1	
			Galactorrhoea	11	0	11	
			Menstrual disorder	1	0	1	
			Amenorrhoea	10	0	9	
			Ovarian cyst	1	0	1	
			Polycystic ovaries	1	0	1	
			Prostatic disorder	1	0	1	
			Genital ulceration	1	0	0	
			Ejaculation failure	1	0	1	
			Erectile dysfunction	4	0	4	
			Priapism	8	0	7	
			Testicular disorder	1	0	1	
			Vaginal haemorrhage	2	0	0	
			Reproductive system and breast disorders	65	0	54	
			Respiratory, thoracic and mediastinal disorders	Asthma	2	1	1
				Bronchospasm	5	0	4
		Bronchial obstruction		1	0	1	
		Pneumonia aspiration		2	1	2	
		Pulmonary fibrosis		2	1	1	
		Pulmonary oedema		1	0	1	
		Infantile apnoeic attack		1	0	0	
		Pleural effusion		1	0	1	
		Pulmonary hypertension		1	0	0	
		Pulmonary embolism		2	1	0	
		Apnoea		2	0	2	
		Dyspnoea		17	2	10	
		Hyperventilation		2	0	0	
		Respiratory arrest		2	0	0	
		Respiratory depression		3	1	2	
Sleep apnoea syndrome	1	0		0			
Tachypnoea	1	0		0			
Hypoxia	2	1		0			

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Medicine	Reaction Count		Case Group	Death Outcomes	Sole	
		Respiratory, thoracic and mediastinal disorders	Cough	4	0	3
			Productive cough	2	0	2
			Respiratory failure	2	0	2
			Respiratory disorder	1	0	1
			Epistaxis	3	0	2
			Nasal polyps	1	0	1
			Respiratory, thoracic and mediastinal disorders	61	8	36
		Skin and subcutaneous tissue disorders	Angioedema	4	0	2
			Periorbital oedema	2	0	2
			Urticaria	13	0	10
			Skin striae	1	0	1
			Leukoplakia	1	0	0
			Blister	2	0	2
			Dermatitis bullous	3	0	3
			Pemphigoid	2	0	2
			Stevens-Johnson syndrome	3	0	3
			Skin discolouration	1	0	1
			Skin odour abnormal	1	0	1
			Skin reaction	1	0	0
			Eczema	1	0	1
			Drug eruption	1	0	1
			Erythema	3	0	2
			Rash erythematous	6	0	6
			Skin exfoliation	2	0	1
			Necrobiosis lipoidica diabetorum	1	0	0
			Photosensitivity reaction	9	0	9
			Pruritus	15	0	9
			Rash pruritic	1	0	0
			Psoriasis	2	0	1
			Rash	38	0	23
			Rash generalised	2	1	2
			Rash macular	3	0	1
			Rash maculo-papular	10	0	8
Rash vesicular	1	0	1			
Acne	9	0	7			
Alopecia	6	0	6			
Hyperhidrosis	27	1	17			
Nail disorder	1	0	1			
Petechiae	1	0	0			
Purpura	7	0	4			
Skin and subcutaneous tissue disorders	180	2	127			
Surgical and medical procedures	Hospitalisation	1	1	1		

olanzapine to end January 2009

			Case Group	Death Outcomes	Sole			
Medicine	Reaction Count	Surgical and medical procedures	Therapy regimen changed	7	0	4		
			Surgical and medical procedures	8	1	5		
		Vascular disorders	Peripheral ischaemia	1	0	0		
			Blood pressure fluctuation	2	0	0		
			Circulatory collapse	5	0	3		
			Shock	1	1	0		
			Hypotension	18	0	12		
			Orthostatic hypotension	14	0	10		
			Arterial thrombosis limb	1	0	1		
			Deep vein thrombosis	3	0	1		
			Vasodilatation	3	0	2		
			Flushing	2	0	2		
			Hot flush	1	0	1		
			Pallor	3	1	1		
			Hypertension	16	1	12		
			Vascular disorders	70	3	45		
			Reaction			2938	116	1734