

ADVERSE DRUG REACTIONS ONLINE INFORMATION TRACKING

DRUG ANALYSIS PRINT

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DRUG : LEVOFLOXACIN
 ROUTE: ALL
 SINGLE-CONSTITUENT PRODS : TAVANIC

MULTI-CONSTITUENT PRODS : NONE

SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	SINGLE CONST TOT	MULTI CONST FTL	SINGLE CONST TOT	MULTI CONST FTL	SYSTEM ORGAN CLASS HIGH LEVEL TERM REACTION NAME	SINGLE CONST TOT	MULTI CONST FTL
Blood and lymphatic system disorders					Diarrhoea (excl infective)		
Anaemias NEC					Diarrhoea	8	0 0 0
Anaemia	1	0	0	0	Dyspeptic signs and symptoms		
Haemolyses NEC					Dyspepsia	2	0 0 0
Haemolysis	1	0	0	0	Flatulence, bloating and distension		
Leukopenias NEC					Abdominal distension	1	0 0 0
Leukopenia	1	0	0	0	Gastrointestinal and abdominal pains (excl oral and throat)		
Lymphopenia	1	0	0	0	Abdominal pain	1	0 0 0
Neutropenias					Abdominal pain upper	2	0 0 0
Neutropenia	2	0	0	0	Gastrointestinal signs and symptoms NEC		
SYS ORGAN CLASS TOTAL:	6	0	0	0	Dysphagia	1	0 0 0
					Nausea and vomiting symptoms		
					Nausea	3	0 0 0
Cardiac disorders					Vomiting	3	0 0 0
Rate and rhythm disorders NEC					Oral soft tissue pain and paraesthesia		
Arrhythmia	1	0	0	0	Oral pain	1	0 0 0
Bradycardia	1	0	0	0	Oral soft tissue signs and symptoms		
Tachycardia	1	0	0	0	Oral mucosal blistering	1	0 0 0
SYS ORGAN CLASS TOTAL:	3	0	0	0	Oral dryness and saliva altered		
					Dry mouth	1	0 0 0
					Tongue signs and symptoms		
Congenital, familial and genetic disorders					Swollen tongue	1	0 0 0
Ocular disorders congenital NEC					SYS ORGAN CLASS TOTAL:	27	1 0 0
Colour blindness	1	0	0	0			
SYS ORGAN CLASS TOTAL:	1	0	0	0	General disorders and administration site conditions		
					Asthenic conditions		
Ear and labyrinth disorders					Asthenia	2	0 0 0
Hearing losses					Malaise	3	0 0 0
Deafness	2	0	0	0	Gait disturbances		
Inner ear signs and symptoms					Difficulty in walking	4	0 0 0
Tinnitus	1	0	0	0	Gait disturbance	1	0 0 0
Vertigo	2	0	0	0	General signs and symptoms NEC		
SYS ORGAN CLASS TOTAL:	5	0	0	0	Chest discomfort	2	0 0 0
					Condition aggravated	1	0 0 0
					Feeling abnormal	3	0 0 0
Eye disorders					Feeling jittery	1	0 0 0
Visual disorders NEC					Mobility decreased	2	0 0 0
Visual disturbance	1	0	0	0	Swelling	4	0 0 0
SYS ORGAN CLASS TOTAL:	1	0	0	0	Inflammatons		
					Inflammation	1	0 0 0
					Oedema NEC		
Gastrointestinal disorders					Gravitational oedema	1	0 0 0
Intestinal haemorrhages					Oedema	1	0 0 0
Rectal haemorrhage	2	1	0	0	Oedema peripheral	5	0 0 0

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Pain and discomfort NEC					
Pain	3	0	Investigations		
Interactions			Heart rate and pulse investigations		
Drug interaction	3	0	Heart rate increased	1	0
Drug interaction potentiation	1	0	Vascular tests NEC (incl blood pressure)		
	---	---	Blood pressure decreased	1	0
SYS ORGAN CLASS TOTAL:	38	0	Tissue enzyme analyses NEC		
	---	---	Blood alkaline phosphatase increased	1	0
Hepatobiliary disorders			Coagulation and bleeding analyses		
Cholestasis and jaundice			International normalised ratio increased	7	0
Jaundice	1	0	Platelet analyses		
Jaundice cholestatic	1	0	Platelet count decreased	1	0
Hepatic failure and associated disorders			Liver function analyses		
Hepatorenal failure	1	0	Alanine aminotransferase increased	1	0
Hepatocellular damage and hepatitis NEC			Aspartate aminotransferase increased	1	0
Hepatitis	2	1	Blood bilirubin increased	2	0
Hepatitis acute	2	0	Gamma-glutamyltransferase increased	1	0
	---	---	Liver function test abnormal	1	0
SYS ORGAN CLASS TOTAL:	7	1	Bacteria identification and serology (excl mycobacteria)		
	---	---	Clostridium difficile toxin test	1	1
Immune system disorders			Renal function analyses		
Allergic conditions NEC			Blood creatinine increased	3	0
Hypersensitivity	3	0	Blood urea increased	1	0
Anaphylactic responses				---	---
Anaphylactic reaction	6	0	SYS ORGAN CLASS TOTAL:	22	1
Anaphylactic shock	1	0		---	---
Anaphylactoid reaction	1	0	Metabolism and nutrition disorders		
	---	---	Diabetes mellitus (incl subtypes)		
SYS ORGAN CLASS TOTAL:	11	0	Diabetes mellitus inadequate control	1	0
	---	---	Hypoglycaemic conditions NEC		
Infections and infestations			Hypoglycaemia	2	0
Clostridia infections			Purine metabolism disorders NEC		
Clostridial infection	1	0	Gout	2	0
Clostridium colitis	3	1		---	---
	---	---	SYS ORGAN CLASS TOTAL:	5	0
SYS ORGAN CLASS TOTAL:	4	1		---	---
	---	---	Musculoskeletal and connective tissue disorders		
Injury, poisoning and procedural complications			Arthropathies NEC		
Cerebral injuries NEC			Arthritis	3	0
Subdural haematoma	1	1	Joint related signs and symptoms		
Muscle, tendon and ligament injuries			Arthralgia	15	0
Epicondylitis	2	0	Joint stiffness	2	0
Tendon injury	1	0	Joint swelling	5	0
Tendon rupture	37	0	Muscle pains		
Non-site specific injuries NEC			Myalgia	10	0
Contusion	4	0	Muscle related signs and symptoms NEC		
Fall	1	0	Muscle cramp	3	0
Peripheral nerve injuries			Muscle twitching	2	0
Peripheral nerve injury	1	0	Muscle weakness conditions		
Radiation injuries			Muscular weakness	2	0
Sunburn	1	0	Myopathies		
	---	---	Rhabdomyolysis	2	0
SYS ORGAN CLASS TOTAL:	48	1	Musculoskeletal and connective tissue signs and symptoms NEC		
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Back pain	1	0	Nervousness	1	0
Musculoskeletal discomfort	1	0	Panic symptoms		0
Musculoskeletal pain	1	0	Panic attack	1	0
Musculoskeletal stiffness	1	0	Increased physical activity levels		0
Pain in extremity	16	0	Restlessness	1	0
Synovial disorders			Confusion and disorientation		0
Synovitis	1	0	Confusional state	4	0
Tenosynovitis	2	0	Disorientation	2	0
Cartilage disorders			Depressive disorders		0
Chondritis	1	0	Depression	1	0
Tendon disorders			Delusional symptoms		0
Tendon disorder	30	0	Delusion	1	0
Tendonitis	155	0	Perception disturbances		0
SYS ORGAN CLASS TOTAL:	253	0	Hallucination	10	0
	---	---	Hallucination, visual	3	0
	---	---	Affect alterations NEC		0
Nervous system disorders			Mood altered	1	0
Headaches NEC			Emotional and mood disturbances NEC		0
Headache	4	0	Crying	1	0
Migraine headaches			Behaviour and socialisation disturbances		0
Migraine	1	0	Aggression	1	0
Dyskinesias and movement disorders NEC			Paranoia	1	0
Movement disorder	1	0	Psychotic disorder NEC		0
Tremor (excl congenital)			Acute psychosis	1	0
Tremor	6	0	Disturbances in initiating and maintaining sleep		0
Cerebellar coordination and balance disturbances			Insomnia	5	0
Ataxia	1	0	Parasomnias		0
Neurological signs and symptoms NEC			Abnormal dreams	1	0
Ageusia	1	0	Nightmare	1	0
Dizziness	4	0	SYS ORGAN CLASS TOTAL:	43	0
Dysgeusia	3	0		---	---
Paraesthesias and dysaesthesias			Renal and urinary disorders		0
Burning sensation	1	0	Renal failure and impairment		0
Hypoaesthesia	1	0	Renal impairment	2	0
Paraesthesia	2	0	SYS ORGAN CLASS TOTAL:	2	0
Speech and language abnormalities				---	---
Dysarthria	2	0	Respiratory, thoracic and mediastinal disorders		0
Neuromuscular junction dysfunction			Bronchospasm and obstruction		0
Myasthenia gravis	1	0	Bronchospasm	2	0
Peripheral neuropathies NEC			Wheezing	1	0
Neuropathy peripheral	1	0	Breathing abnormalities		0
Generalised tonic-clonic seizures			Dyspnoea	5	0
Grand mal convulsion	3	0	Hyperventilation	1	0
Seizures and seizure disorders NEC			Coughing and associated symptoms		0
Convulsion	3	0	Cough	1	0
Epilepsy	4	0	Upper respiratory tract signs and symptoms		0
SYS ORGAN CLASS TOTAL:	39	0	Throat tightness	2	0
	---	---	Laryngeal spasm, oedema and obstruction		0
	---	---	Laryngeal oedema	1	0
Psychiatric disorders			Pharyngeal disorders (excl infections and neoplasms)		0
Anxiety symptoms			Oropharyngeal swelling	1	0
Agitation	5	0			0
Anxiety	2	0			0

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SYS ORGAN CLASS TOTAL:	14	0	Pallor	1	0
Skin and subcutaneous tissue disorders			Accelerated and malignant hypertension	1	0
Angioedemas			Malignant hypertension		
Angioneurotic oedema	3	0	SYS ORGAN CLASS TOTAL:	8	1
Face oedema	1	0	TOTAL REACTIONS FOR DRUG:	580	6
Urticarias				0	0
Urticaria	9	0	TOTAL REPORTS: 395		
Urticaria generalised	1	0	TOTAL FATAL OUTCOME: 6		
Bullous conditions			*** END OF REPORT ***		
Erythema multiforme	1	0			
Dermal and epidermal conditions NEC					
Skin lesion	1	0			
Swelling face	2	0			
Dermatitis and eczema					
Dermatitis allergic	1	0			
Erythemas					
Erythema	2	0			
Rash erythematous	2	0			
Exfoliative conditions					
Skin desquamation	1	0			
Papulosquamous conditions					
Rash papular	1	0			
Pruritus NEC					
Pruritus	2	0			
Rash pruritic	2	0			
Rashes, eruptions and exanthems NEC					
Rash	3	0			
Rash generalised	5	0			
Apocrine and eccrine gland disorders					
Hyperhidrosis	2	0			
Purpura and related conditions					
Purpura	1	0			
Skin vasculitides					
Vasculitic rash	2	0			
SYS ORGAN CLASS TOTAL:	42	0			
Social circumstances					
Disability issues					
Immobile	1	0			
SYS ORGAN CLASS TOTAL:	1	0			
Vascular disorders					
Vascular hypotensive disorders					
Hypotension	4	0			
Peripheral embolism and thrombosis					
Deep vein thrombosis	1	1			
Peripheral vascular disorders NEC					
Flushing	1	0			
Site specific vascular disorders NEC					