

ADVERSE DRUG REACTIONS ONLINE INFORMATION TRACKING

DRUG ANALYSIS PRINT

PAGE: 1

DRUG : NALIDIXIC ACID
 ROUTE: ALL
 SINGLE-CONSTITUENT PRODS : NEGRAM

MULTI-CONSTITUENT PRODS : MICTRAL (CITRIC ACID, SODIUM BICARBONATE, SODIUM CITRATE)

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					Vertigo	27	0
Marrow depression and hypoplastic anaemias						---	---
Aplastic anaemia	1	0	0	0	SYS ORGAN CLASS TOTAL:	32	0
Pancytopenia	1	0	0	0		---	---
Anaemias haemolytic NEC					Endocrine disorders		
Coombs negative haemolytic anaemia	1	0	0	0	Female gonadal function disorders		
Thrombocytopenias					Virilism	2	0
Idiopathic thrombocytopenic purpura	2	0	0	0		---	---
Thrombocytopenia	13	0	0	0	SYS ORGAN CLASS TOTAL:	2	0
Lymphatic system disorders NEC						---	---
Lymphadenopathy	2	0	0	0	Eye disorders		
Leukocytoses NEC					Corneal structural change, deposit and degeneration		
Eosinophilia	2	0	0	0	Xerophthalmia	1	0
Neutropenias					Ocular disorders NEC		
Granulocytopenia	1	0	0	0	Eye disorder	1	0
SYS ORGAN CLASS TOTAL:	23	0	0	0	Conjunctival infections, irritations and inflammations		
	---	---	---	---	Conjunctivitis	2	0
Cardiac disorders					Iris and uveal tract infections, irritations and inflammations		
Rate and rhythm disorders NEC					Uveitis	1	0
Extrasystoles	1	0	0	0	Eyelid movement disorders		
Tachycardia	12	0	0	0	Eyelid ptosis	1	0
Ventricular arrhythmias and cardiac arrest					Ocular nerve and muscle disorders		
Cardiac arrest	0	0	1	0	Strabismus	2	0
Cardiac signs and symptoms NEC					Pupil disorders		
Cyanosis	2	0	0	0	Miosis	2	0
Palpitations	11	0	0	0	Mydriasis	4	0
Ischaemic coronary artery disorders					Pupillary reflex impaired	2	0
Angina pectoris	1	0	0	0	Ocular sensation disorders		
SYS ORGAN CLASS TOTAL:	27	0	1	0	Photophobia	46	0
	---	---	---	---	Optic disc abnormalities NEC		
Congenital, familial and genetic disorders					Papilloedema	5	0
Congenital disorders NEC					Retinal bleeding and vascular disorders (excl retinopathy)		
Congenital anomaly	1	0	0	0	Retinal haemorrhage	1	0
Musculoskeletal and connective tissue disorders of limbs congenit					Retinal vascular disorder	1	0
Congenital hand malformation	1	0	0	0	Blindness (excl colour blindness)		
SYS ORGAN CLASS TOTAL:	2	0	0	0	Blindness transient	1	0
	---	---	---	---	Refractive and accommodative disorders		
Ear and labyrinth disorders					Accommodation disorder	11	0
Hearing disorders NEC					Visual disorders NEC		
Hearing impaired	1	0	0	0	Diplopia	8	0
Inner ear signs and symptoms					Visual disturbance	426	0
Tinnitus	4	0	0	0	Visual field disorders		
	---	---	---	---	Scotoma	1	0
	---	---	---	---	SYS ORGAN CLASS TOTAL:	516	0

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PAGE: 2

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	---	---	---	---	Gait disturbance	2	0	0	0
Gastrointestinal disorders					Oedema NEC				
Anal and rectal signs and symptoms					Generalised oedema	3	0	0	0
Pruritus ani	1	0	0	0	Oedema	5	0	1	0
Non-site specific gastrointestinal haemorrhages					Oedema peripheral	3	0	1	0
Gastrointestinal haemorrhage	1	0	0	0	Pain and discomfort NEC				
Haematemesis	0	0	1	0	Chest pain	7	0	1	0
Oesophagitis (excl infective)					Pain	1	0	0	0
Oesophagitis	1	0	0	0	Interactions				
Diarrhoea (excl infective)					Drug interaction	4	0	0	0
Diarrhoea	19	0	2	0	Drug interaction inhibition	1	0	0	0
Dyspeptic signs and symptoms					Drug interaction potentiation	1	0	0	0
Dyspepsia	3	0	0	0	Food interaction	2	0	0	0
Flatulence, bloating and distension					Therapeutic and nontherapeutic responses				
Abdominal distension	1	0	0	0	Drug ineffective	0	0	1	0
Flatulence	1	0	0	0	Unexpected therapeutic drug effect	1	0	0	0
Gastrointestinal and abdominal pains (excl oral and throat)						---	---	---	---
Abdominal pain	10	0	2	0	SYS ORGAN CLASS TOTAL:	72	0	6	0
Gastrointestinal signs and symptoms NEC						---	---	---	---
Dysphagia	1	0	0	0	Hepatobiliary disorders				
Faecal incontinence	1	0	0	0	Cholestasis and jaundice				
Nausea and vomiting symptoms					Hepatitis cholestatic	1	0	0	0
Nausea	74	0	3	0	Jaundice	7	0	1	0
Vomiting	51	0	5	0	Hepatic enzymes and function abnormalities				
Duodenal ulcers and perforation					Hepatic function abnormal	0	0	1	0
Duodenal ulcer haemorrhage	1	0	0	0	Hepatocellular damage and hepatitis NEC				
Oral soft tissue disorders NEC					Hepatic necrosis	1	1	0	0
Cheilitis	1	0	0	0	Hepatitis	1	1	0	0
Oral soft tissue signs and symptoms					Hepatocellular damage	1	0	1	0
Hypoaesthesia oral	1	0	0	0		---	---	---	---
Stomatitis and ulceration					SYS ORGAN CLASS TOTAL:	11	2	3	0
Mouth ulceration	1	0	0	0		---	---	---	---
Stomatitis	3	0	0	0	Immune system disorders				
Oral dryness and saliva altered					Allergic conditions NEC				
Dry mouth	2	0	0	0	Hypersensitivity	1	0	1	0
Tongue disorders NEC					Anaphylactic responses				
Glossitis	6	0	0	0	Anaphylactic reaction	15	0	8	0
Tongue signs and symptoms					Anaphylactic shock	0	0	1	0
Swollen tongue	0	0	1	0	Anaphylactoid reaction	6	0	4	0
Tongue oedema	1	0	0	0		---	---	---	---
	---	---	---	---	SYS ORGAN CLASS TOTAL:	22	0	14	0
SYS ORGAN CLASS TOTAL:	180	0	14	0		---	---	---	---
	---	---	---	---	Infections and infestations				
General disorders and administration site conditions					Dental and oral soft tissue infections				
Body temperature perception					Dental caries	1	0	0	0
Chills	5	0	0	0	Upper respiratory tract infections				
Febrile disorders					Pharyngitis	3	0	0	0
Pyrexia	10	0	1	0		---	---	---	---
Asthenic conditions					SYS ORGAN CLASS TOTAL:	4	0	0	0
Asthenia	4	0	1	0		---	---	---	---
Fatigue	3	0	0	0	Injury, poisoning and procedural complications				
Malaise	20	0	0	0	Muscle, tendon and ligament injuries				
Gait disturbances					Tendon injury	1	0	0	0

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PAGE: 3

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Tendon rupture	1	0	Muscle pains		
Skin injuries NEC			Myalgia	16	0
Blister	3	0	Muscle related signs and symptoms NEC		1
	---	---	Muscle cramp	1	0
SYS ORGAN CLASS TOTAL:	5	0	Muscle twitching	2	0
	---	---	Muscle weakness conditions		
Investigations			Muscular weakness	9	0
ECG investigations			Myopathies		
Electrocardiogram abnormal	1	0	Myopathy	2	0
Pituitary analyses posterior			Musculoskeletal and connective tissue signs and symptoms NEC		
Blood antidiuretic hormone increased	1	0	Back pain	1	0
Coagulation and bleeding analyses			Dupuytren's contracture	1	0
International normalised ratio increased	1	0	Muscle spasms	1	0
Prothrombin level decreased	1	0	Synovial disorders		
Haematological analyses NEC			Synovitis	2	0
Red blood cell sedimentation rate increased	2	0	Tendon disorders		
Neurologic diagnostic procedures			Tendonitis	3	0
Electroencephalogram abnormal	1	0		---	---
Physical examination procedures			SYS ORGAN CLASS TOTAL:	71	0
Weight decreased	1	0		---	---
Weight increased	1	0	Nervous system disorders		
	---	---	Olfactory nerve disorders		
SYS ORGAN CLASS TOTAL:	9	0	Parosmia	1	0
	---	---	Optic nerve disorders NEC		
Metabolism and nutrition disorders			Optic neuritis	2	0
Metabolic acidoses (excl diabetic acidoses)			Encephalopathies NEC		
Metabolic acidosis	1	0	Encephalopathy	1	0
Mixed acid-base disorders			Headaches NEC		
Acidosis	5	0	Headache	74	0
Appetite disorders			Migraine headaches		
Anorexia	2	0	Migraine	7	0
Increased appetite	1	0	Increased intracranial pressure disorders		
Food malabsorption and intolerance syndromes (excl sugar intolera			Intracranial pressure increased	10	1
Alcohol intolerance	1	0	Memory loss (excl dementia)		
Hyperglycaemic conditions NEC			Amnesia	1	0
Hyperglycaemia	1	0	Mental impairment (excl dementia and memory loss)		
Purine metabolism disorders NEC			Disturbance in attention	4	0
Gout	1	0	Choreiform movements		
	---	---	Choreoathetosis	1	0
SYS ORGAN CLASS TOTAL:	12	0	Dyskinesias and movement disorders NEC		
	---	---	Extrapyramidal disorder	1	0
Musculoskeletal and connective tissue disorders			Hyperkinesia	2	0
Bone related signs and symptoms			Dystonias		
Pain in jaw	0	0	Dystonia	2	0
Lupus erythematosus (incl subtypes)			Paralysis and paresis (excl congenital and cranial nerve)		
Systemic lupus erythematosus	1	0	Hemiparesis	1	0
Arthropathies NEC			Paralysis	1	0
Arthritis	2	0	Paresis	2	0
Arthropathy	7	0	Quadriplegia	1	0
Joint related signs and symptoms			Tremor (excl congenital)		
Arthralgia	22	0	Tremor	13	0
Muscle infections and inflammations			Abnormal reflexes		
Myositis	1	0	Hyporeflexia	2	0

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PAGE: 4

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Cerebellar coordination and balance disturbances					Depression	12	0
Ataxia	12	0	0	0	Dissociative states		
Coordination abnormal	4	0	0	0	Depersonalisation	8	0
Nystagmus	2	0	0	0	Delusional symptoms		
Coma states					Delusion	1	0
Coma	4	1	1	0	Perception disturbances		
Disturbances in consciousness NEC					Hallucination	27	0
Lethargy	1	0	0	0	Hallucinations, mixed	2	0
Loss of consciousness	3	0	0	0	Thinking disturbances		
Somnolence	19	0	0	0	Thinking abnormal	5	0
Stupor	4	0	0	0	Mood alterations with manic symptoms		
Syncope	45	0	1	0	Mania	4	0
Neurological signs and symptoms NEC					Affect alterations NEC		
Dizziness	108	0	1	0	Affect lability	3	0
Paraesthesias and dysaesthesias					Emotional and mood disturbances NEC		
Hyperaesthesia	1	0	0	0	Euphoric mood	3	0
Hypoesthesia	2	0	0	0	Behaviour and socialisation disturbances		
Paraesthesia	24	0	2	0	Paranoia	2	0
Sensory abnormalities NEC					Personality disorders NEC		
Sensory disturbance	13	0	0	0	Personality disorder	3	0
Speech and language abnormalities					Psychiatric symptoms NEC		
Dysphasia	1	0	0	0	Drug dependence	2	0
Speech disorder	1	0	0	0	Psychotic disorder NEC		
Neurologic visual problems NEC					Psychotic disorder	9	0
Hemianopia	1	0	0	0	Disturbances in initiating and maintaining sleep		
Visual field defect	4	0	0	0	Insomnia	2	0
Peripheral neuropathies NEC					Parasomnias		
Neuropathy peripheral	1	0	0	0	Nightmare	1	0
Peripheral sensory neuropathy	1	0	0	0			
Generalised tonic-clonic seizures					SYS ORGAN CLASS TOTAL:	117	0
Grand mal convulsion	13	0	0	0			
Seizures and seizure disorders NEC					Renal and urinary disorders		
Convulsion	14	0	1	0	Renal failure and impairment		
	---	---	---	---	Renal impairment	1	0
SYS ORGAN CLASS TOTAL:	404	2	6	0	Bladder and urethral symptoms		
	---	---	---	---	Incontinence	0	0
Pregnancy, puerperium and perinatal conditions					Urinary incontinence	3	0
Neonatal hepatobiliary disorders					Urinary abnormalities		
Jaundice neonatal	1	0	0	0	Glycosuria	1	0
	---	---	---	---	Haematuria	3	0
SYS ORGAN CLASS TOTAL:	1	0	0	0		---	---
	---	---	---	---	SYS ORGAN CLASS TOTAL:	8	0
Psychiatric disorders						---	---
Anxiety symptoms					Reproductive system and breast disorders		
Agitation	4	0	0	0	Breast disorders NEC		
Anxiety	6	0	0	0	Gynaecomastia	0	0
Fear symptoms					Menstruation and uterine bleeding NEC		
Fear	1	0	0	0	Menstruation irregular	1	0
Confusion and disorientation					Ovarian and fallopian tube disorders NEC		
Confusional state	19	0	0	0	Ovarian disorder	1	0
Deliria					Erection and ejaculation conditions and disorders		
Delirium	3	0	0	0	Erectile dysfunction	1	0
Depressive disorders						---	---

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SYS ORGAN CLASS TOTAL:	3	0	Psoriasis	2	0
Respiratory, thoracic and mediastinal disorders	---	---	Photosensitivity conditions	8	0
Bronchospasm and obstruction	---	---	Photosensitivity allergic reaction	74	0
Asthma	2	0	Photosensitivity reaction	18	0
Bronchospasm	4	0	Pruritus NEC	2	0
Lower respiratory tract inflammatory and immunologic conditions	---	---	Pruritus	2	0
Alveolitis	1	0	Rash pruritic	77	0
Parenchymal lung disorders NEC	---	---	Rashes, eruptions and exanthems NEC	21	0
Pulmonary fibrosis	3	0	Rash	16	0
Breathing abnormalities	---	---	Rash maculo-papular	1	0
Apnoeic attack	1	0	Rash morbilliform	1	0
Dyspnoea	13	0	Rash vesicular	16	0
Hyperventilation	1	0	Pigmentation changes NEC	1	0
Conditions associated with abnormal gas exchange	---	---	Skin discolouration	16	0
Respiratory gas exchange disorder	1	0	Acnes	1	0
Coughing and associated symptoms	---	---	Acne	1	0
Cough	1	0	Alopecias	2	0
Lower respiratory tract signs and symptoms	---	---	Alopecia	2	0
Increased bronchial secretion	1	0	Hypotrichosis	5	0
Respiratory failures (excl neonatal)	---	---	Apocrine and eccrine gland disorders	1	0
Acute respiratory failure	0	0	Hyperhidrosis	7	0
Laryngeal spasm, oedema and obstruction	---	---	Purpura and related conditions	7	0
Laryngeal oedema	1	0	Purpura	---	---
Nasal disorders NEC	---	---	SYS ORGAN CLASS TOTAL:	399	1
Epistaxis	0	0	Surgical and medical procedures	---	---
SYS ORGAN CLASS TOTAL:	29	0	Anaesthesia and allied procedures	1	0
Skin and subcutaneous tissue disorders	---	---	Local anaesthesia	---	---
Angioedemas	---	---	SYS ORGAN CLASS TOTAL:	1	0
Angioneurotic oedema	7	0	Vascular disorders	---	---
Face oedema	13	0	Vascular hypotensive disorders	13	0
Periorbital oedema	4	0	Hypotension	1	0
Urticarias	---	---	Orthostatic hypotension	2	0
Urticaria	77	0	Peripheral embolism and thrombosis	2	0
Skin hyperplasias and hypertrophies	---	---	Thrombophlebitis superficial	10	0
Skin hypertrophy	1	0	Peripheral vascular disorders NEC	3	0
Bullous conditions	---	---	Flushing	1	0
Dermatitis bullous	11	0	Site specific vascular disorders NEC	---	---
Erythema multiforme	5	0	Pallor	30	0
Pemphigoid	2	0	Vascular hypertensive disorders NEC	---	---
Stevens-Johnson syndrome	1	0	Hypertension	1	0
Toxic epidermal necrolysis	2	0	SYS ORGAN CLASS TOTAL:	---	---
Dermatitis and eczema	---	---	TOTAL REACTIONS FOR DRUG:	1980	5
Dermatitis	1	0	TOTAL REPORTS: 1,233	81	0
Eczema	1	0	TOTAL FATAL OUTCOME:	---	---
Erythemas	---	---	*** END OF REPORT ***	---	---
Erythema	1	0		---	---
Rash erythematous	17	0		---	---
Exfoliative conditions	---	---		---	---
Dermatitis exfoliative	4	1		---	---
Papulosquamous conditions	---	---		---	---