

- for internal Lilly use only

→ Rhabdomyolysis

Olanzapine Spontaneous Reports in Clintrace, entered through

30-Sep-1998

CASES = 7,193 Unduplicated Reports in Time Period Selected

(P. 4)

Costart Term	Reports	Events
ABDOMEN ENLARGED	11	11
ABDOMINAL PAIN	54	54
ABDOMINAL SYNDROME ACUTE	1	1
ABNORMAL DREAMS	36	36
ABNORMAL EJACULATION	11	11
ABNORMAL ELECTROENCEPHALOGRAM	29	29
ABNORMAL GAIT	81	81
ABNORMAL LABOR	1	1
ABNORMAL PLATELETS	1	1
ABNORMAL STOOLS	5	5
ABNORMAL VISION	42	43
ABNORMALITY OF ACCOMMODATION	4	4
ABORTION	8	8
ABSCESS	1	1
ACCIDENTAL INJURY	58	59
ACCIDENTAL OVERDOSE	20	20
ACIDOSIS	3	3
ACNE	22	22
ACUTE BRAIN SYNDROME	4	4
ACUTE KIDNEY FAILURE	7	7
ACUTE LEUKEMIA	1	1
ADH INAPPROPRIATE	4	4
AGGRAVATION REACTION	3	3
AGITATION	224	224
AGRANULOCYTOSIS	5	5
AIDS	1	1
AKATHISIA	133	133
AKINESIA	8	9
ALBUMINURIA	8	8
ALCOHOL INTOLERANCE	3	3
ALKALINE PHOSPHATASE INCREASED	35	35
ALLERGIC REACTION	27	27
ALOPECIA	84	84
AMBLYOPIA	45	45
AMENORRHEA	52	52
AMNESIA	45	45
AMYLASE INCREASED	8	8
ANAPHYLACTOID REACTION	2	2
ANEMIA	23	23
ANGIOEDEMA	9	9

* DM
KMS

ZY 1946 487

OlanEvtCnt.rep

1

7/16/1999

JUL 18 1999 17:10

3175782801

PAGE.03

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

ANISOCORIA	1	1
ANOREXIA	30	30
ANORGASMIA	4	4
ANTICHOLINERGIC SYNDROME	2	2
ANTINUCLEAR ANTIBODY PRESENT	3	3
ANTISOCIAL REACTION	1	1
ANURIA	4	4
ANXIETY	97	97
AORTIC STENOSIS	1	1
APATHY	31	31
APHASIA	1	1
APLASTIC ANEMIA	4	4
APNEA	38	38
ARRHYTHMIA	22	22
ARTERIOSCLEROSIS	7	7
ARTHRALGIA	51	51
ARTHRITIS	5	5
ARTHROSIS	6	6
ASCITES	1	1
ASPHYXIA	2	2
ASPIRATION PNEUMONIA	6	6
ASTHENIA	167	168
ASTHMA	17	17
ATAXIA	34	34
ATRIAL FIBRILLATION	11	11
ATRIAL FLUTTER	1	1
AV BLOCK	2	2
AV BLOCK SECOND DEGREE	1	1
AVITAMINOSIS	1	1
B12 DEFICIENCY ANEMIA	1	1
BACK PAIN	31	31
BILIRUBINEMIA	33	33
BILIRUBINURIA ✓	1	1
? blank	3	3
BLEEDING TIME INCREASED	1	1
BLEPHARITIS	2	2
BLOOD DYSCRASIA	2	2
BODY ODOR	2	2
BONE DISORDER	2	2
BONE PAIN	4	4
BRADYCARDIA	28	28

ZY 1946 488

OlanEviCnt.rep

2

7/18/1999

JUL 18 1999 17:10

3175782801

PAGE.04

WORKING DRAFT

for internal Lilly use only

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

BRAIN EDEMA	7	7
BREAST ATROPHY	1	1
BREAST ENLARGEMENT	9	9
BREAST NEOPLASM	1	1
BREAST PAIN	21	21
BRONCHITIS	2	2
BUCCOGLOSSAL SYNDROME	19	19
BUN INCREASED	9	9
BUNDLE BRANCH BLOCK	7	7
CARCINOMA	3	3
CARDIOMEGALY	2	2
CARDIOMYOPATHY	3	3
CARDIOVASCULAR DISORDER	15	15
CATARACT NOS	3	3
CATARACT SPECIFIED	3	3
CATATONIC REACTION	9	9
CELLULITIS	6	6
CEREBRAL HEMORRHAGE	2	2
CEREBRAL ISCHEMIA	2	2
CEREBROVASCULAR ACCIDENT	10	10
CEREBROVASCULAR DISORDER	1	1
CHEST PAIN	47	47
CHEST PAIN SUBSTERNAL	1	1
CHILLS	30	30
CHILLS AND FEVER	1	1
CHOLECYSTITIS	1	1
CHOLELITHIASIS	4	4
CHOLESTATIC JAUNDICE	2	2
CHOREOATHETOSIS	11	11
CHROMATOPSIA	1	1
CIRRHOSIS OF LIVER	1	1
CNS CONGENITAL ANOMALY	1	1
CNS DEPRESSION	3	3
CNS STIMULATION	11	12
COAGULATION DISORDER	3	3
COGWHEEL RIGIDITY	32	32
COLITIS	2	2
COLOR BLINDNESS	1	1
COMA	75	75
CONFUSION	151	155
CONGENITAL ANOMALY	2	2

OlanEviCnt.rep

3

7/16/1999

ZY 1946 489

JUL 18 1999 17:11

3175782801

PAGE.05

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

CONGESTIVE HEART FAILURE	10	10
CONJUNCTIVITIS	16	16
CONSTIPATION	50	50
CONVULSION	153	154
COR PULMONALE	2	2
CORONARY ARTERY DISORDER	8	8
CORONARY OCCLUSION	1	1
COUGH INCREASED	12	12
CREATINE PHOSPHOKINASE INCREASED	161	161
CREATININE INCREASED	17	17
CYANOSIS	5	5
CYST	3	3
CYSTITIS	2	2
DEAFNESS	8	8
DEATH	40	40
DEEP THROMBOPHLEBITIS	10	10
DEHYDRATION	11	11
DELIRIUM	47	47
DELUSIONS	54	54
DEMENTIA	2	2
DEPERSONALIZATION	16	16
DEPRESSION	92	94
DIABETES INSIPIDUS	3	3
DIABETES MELLITUS ✓	48	48
DIABETIC ACIDOSIS ✓	24	24
DIABETIC COMA	2	2
DIARRHEA	67	67
DIPLOPIA	6	6
DISSEMINATED INTRAVASCULAR COAGULATION	1	1
DIZZINESS	152	152
DRUG DEPENDENCE	1	1
DRUG INTERACTION	95	95
DRUG LEVEL DECREASED	20	20
DRUG LEVEL INCREASED	25	25
DRY EYES	8	8
DRY MOUTH	51	51
DRY SKIN	8	8
DYSARTHRIA	12	12
DYSKINESIA	61	62
DYSMENORRHEA	1	1
DYSPEPSIA	12	13

PNMS

*OH ✓
*OH ✓
*OH ✓
-NMS

ZY 1946 490

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

DYSPHAGIA	47	47
DYSPNEA	143	143
DYSTONIA	74	74
DYSURIA	8	8
EAR DISORDER	1	1
EAR PAIN	3	3
ECCHYMOSIS	12	12
ECZEMA	10	10
EDEMA	130	131
ELECTROCARDIOGRAM ABNORMAL	28	28
ELECTROLYTE ABNORMALITY	3	3
ELECTROLYTE DEPLETION	1	1
EMOTIONAL LABILITY	26	26
ENCEPHALITIS	1	1
ENCEPHALOPATHY	4	4
ENLARGED CLITORIS	1	1
ENZYMATIC ABNORMALITY	1	1
EOSINOPHILIA	25	25
EOSINOPHILIC PNEUMONIA	1	1
EPISTAXIS	22	22
ERUCTATION	2	2
ERYTHEMA MULTIFORME	4	4
ERYTHROCYTES ABNORMAL	6	8
ESOPHAGITIS	2	2
EUPHORIA	24	24
EXFOLIATIVE DERMATITIS	5	5
EXOPHTHALMOS	2	2
EXTRAPYRAMIDAL SYNDROME	148	148
EXTRASYSTOLES	2	2
EYE DISORDER	25	25
EYE HEMORRHAGE	2	2
EYE PAIN	17	17
FACE EDEMA	146	147
FACIAL PARALYSIS	9	9
FECAL IMPACTION	2	2
FECAL INCONTINENCE	15	15
FEMALE LACTATION	56	57
FETAL DISORDER	1	1
FEVER	227	228
FIBROCYSTIC BREAST	3	3
FLATULENCE	24	24

OlanEvtCnt.rep

5

7/16/1999

JUL 18 1999 17:12

3175782801

PAGE.07

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

FLU SYNDROME	23	23
FOOT DROP	1	1
FUNGAL DERMATITIS	1	1
FURUNCULOSIS	1	1
L GAMMA GLUTAMYL TRANSPEPTIDASE INCREASED ✓	56	56
GASTRITIS	4	4
GASTROENTERITIS	1	1
GASTROINTESTINAL CARCINOMA	3	3
GASTROINTESTINAL DISORDER	14	14
GASTROINTESTINAL HEMORRHAGE	2	2
GENERALIZED EDEMA	20	20
GENERALIZED SPASM	3	3
GENITAL EDEMA	2	2
GINGIVITIS	6	6
GLAUCOMA	4	4
GLOBULIN INCREASED	1	1
GLOSSITIS	10	10
GLUCOCORTICIDS INCREASED	1	1
*DM *DT GLUCOSE TOLERANCE DECREASED	1	1
GLYCOSURIA ✓	6	6
GOITER	2	2
GOUT	1	1
GRAND MAL CONVULSION	58	58
GRANULOCYTOSIS	1	1
GUM HEMORRHAGE	1	1
GYNECOMASTIA	26	27
HAIR DISORDER	4	4
HALLUCINATIONS	150	151
HANGOVER EFFECT	2	2
HEADACHE	104	104
HEART ARREST	31	31
HEART BLOCK	1	1
HEART FAILURE	13	13
HEMATEMESIS	8	8
HEMATURIA	17	17
HEMOLYSIS	1	1
HEMOLYTIC ANEMIA	3	3
HEMORRHAGE	5	5
HEMORRHAGE OF COLON	1	1
HEMORRHAGIC CYSTITIS	1	1
HEMORRHAGIC PANCREATITIS	2	2

*DM
*DT

ZY 1946 492

OlanEvtCnt.rep

6

7/16/1999

JUL 18 1999 17:12

3175782801

PAGE.08

Zyprexa MDL 1596 Confidential-Subject to Protective Order

ZY1 00361915

Zyprexa MDL Plaintiffs' Exhibit No.01394

Page 6

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

L	HEPATIC COMA	1	1
L	HEPATIC FAILURE ✓	9	9
L	HEPATITIS ✓	19	19
	HEPATITIS B POSITIVE SA	1	1
L	HEPATOMEGALY ✓	3	3
	HERNIA	1	1
	HERPES ZOSTER	2	2
	HICCUP	5	5
	HIGH DENSITY LIPOPROTEIN DECREASED	1	1
	HIRSUTISM	5	5
	HORMONE LEVEL ALTERED	13	13
	HOSTILITY	151	151
	HYPERACUSIS	2	2
	HYPERCALCEMIA	3	3
	HYPERCHLOREMIA	1	1
	HYPERCHOLESTEREMIA	12	12
	HYPERESTHESIA	1	1
*DM	HYPERGLYCEMIA ✓	152	152
	HYPERKALEMIA	4	4
	HYPERKINESIA	37	37
	HYPERLIPEMIA	18	18
	HYPERNATREMIA	8	8
	HYPERPHOSPHATEMIA	2	2
	HYPERTENSION	101	101
	HYPERTHYROIDISM	4	4
	HYPERTONIA	171	174
	HYPERURICEMIA	4	4
	HYPERVENTILATION	27	27
	HYPERVOLEMIA	1	1
	HYPESTHESIA	12	12
	HYPOCALCEMIA	1	1
	HYPOCHOLESTEREMIA	1	1
	HYPOCHROMIC ANEMIA	2	2
	HYPOGLYCEMIA	14	14
	HYPOKALEMIA	14	14
	HYPOKINESIA	7	7
	HYPOMAGNESEMIA	1	1
	HYPONATREMIA	39	39
	HYPOPHOSPHATEMIA	1	1
L	HYPOPROTEINEMIA	12	12
	HYPOTENSION	102	102

OlanEvtCnt.rep

7

7/16/1998

JUL 18 1999 17:13

3175782801

PAGE.09

ZY 1946 493

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

HYPOTHERMIA	18	18
HYPOTHYROIDISM	8	8
HYPOTONIA	7	7
HYPOVENTILATION	13	13
HYPOXIA	4	4
ICHTHYOSIS	1	1
ILEUS	3	3
IMMUNE SYSTEM DISORDER	3	3
IMPOTENCE	31	31
INCOORDINATION	27	27
INCREASED ANTICOAGULANT EFFECT	2	2
INCREASED APPETITE	128	128
INCREASED SALIVATION	86	86
INFECTION	17	17
INFECTION FUNGAL	3	3
INSOMNIA	119	119
INTENTIONAL INJURY	13	13
INTENTIONAL OVERDOSE	349	350
INTERSTITIAL PNEUMONIA	3	3
INTESTINAL OBSTRUCTION	6	6
INTRACRANIAL HYPERTENSION	1	1
IRITIS	1	1
JAUNDICE ✓	29	29
JOINT DISORDER	31	31
*DM KETOSIS ✓	9	9
KIDNEY CORTEX NECROSIS	1	1
KIDNEY FAILURE	12	12
KIDNEY FUNCTION ABNORMAL	10	10
KIDNEY PAIN	2	2
KIDNEY TUBULAR NECROSIS	1	1
LAB TEST ABNORMAL	25	25
LABIAL EDEMA	1	1
LABORATORY TEST INTERFERENCE	3	3
LACK OF DRUG EFFECT	246	247
LACRIMATION DISORDER	2	2
*DM LACTIC ACIDOSIS	4	4
LACTIC DEHYDROGENASE INCREASED	15	15
LARYNGISMUS	7	7
LARYNGITIS	1	1
LARYNX EDEMA	1	1
LE SYNDROME	4	4

OlanEvtCnt.rep

8

7/16/1999

JUL 18 1999 17:13

3175782801

PAGE.10

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

LEG CRAMPS	14	14
LEUKEMIA	2	2
LEUKOCYTOSIS	54	54
LEUKODERMA	2	2
LEUKOPENIA	191	196
LEUKORRHEA	1	1
LIBIDO DECREASED	15	15
LIBIDO INCREASED	16	16
LICHENOID DERMATITIS	1	1
LIPASE INCREASED	2	2
LIVER DAMAGE	4	4
LIVER FATTY DEPOSIT ✓	4	4
LIVER FUNCTION TESTS ABNORMAL ✓	177	178
LIVER TENDERNESS	1	1
LUNG DISORDER	6	6
LUNG EDEMA	13	13
LUNG FIBROSIS	2	2
LYMPHADENOPATHY	9	9
LYMPHOCYTOSIS	3	3
LYMPHOMA LIKE REACTION	2	2
MACROCYTIC ANEMIA	1	1
MACULOPAPULAR RASH	24	24
MALaise	46	46
MALE LACTATION	5	5
MANIC DEPRESSIVE REACTION	4	4
MANIC REACTION	102	102
MARROW DEPRESSION	4	4
MASKED FACIES	3	3
MASTITIS	2	2
MELENA	2	2
MENORRHAGIA	13	13
MENSTRUAL DISORDER	19	19
MENTAL RETARDATION	2	2
METRORRHAGIA	13	14
MIGRAINE	12	12
MIOSIS	12	12
MONILIASIS	1	1
MONOCYTOSIS	2	2
MOUTH ULCERATION	9	9
MOVEMENT DISORDER	86	87
MUCOUS MEMBRANE DISORDER	1	1

OlanEviCnt.rep

9

7/16/1999

JUL 18 1999 17:14

3175782801

PAGE.11

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

MUSCLE ATROPHY	1	1
MYALGIA	62	64
MYASTHENIA	13	13
MYDRIASIS	5	5
MYOCARDIAL INFARCT	17	17
MYOCARDIAL ISCHEMIA	1	1
MYOCARDITIS	3	3
MYOCLONUS	23	23
MYOPATHY ✓	15	15
MYOSITIS	1	1
NAIL DISORDER	7	7
NAUSEA	94	94
NAUSEA AND VOMITING	20	20
NECK PAIN	8	8
NECK RIGIDITY	19	19
NEPHRITIS	1	1
NEPHROSIS	3	3
NERVOUSNESS	150	152
NEURALGIA	3	3
NEUROLEPTIC MALIGNANT SYNDROME ✓	112	112
NEUROPATHY	6	6
NEUROSIS	25	25
NEUROTRANSMITTER LEVEL ALTERED	6	6
NIGHT BLINDNESS	1	1
NOCTURIA	2	2
NPN INCREASED	4	4
NYSTAGMUS	4	4
OCULOGYRIC CRISIS	20	20
OLIGURIA	3	3
OPHTHALMOPLEGIA	1	1
OPISTHOTONOS	3	3
ORAL MONILIASIS	1	1
OVERDOSE	145	145
PAIN	76	76
PALLOR	11	11
PALPITATION	19	19
PANCREAS DISORDER	2	2
PANCREATITIS	12	12
PANCYTOPENIA	8	8
PAPILLEDEMA	3	3
PARALYSIS	9	9

VHS

VHS

ZY 1946 496

OlanEvtCnt.rep

10

7/16/1999

JUL 18 1999 17:14

3175782801

PAGE.12

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

PARANOID REACTION	42	42
PARESTHESIA	74	76
PAROSMIA	4	4
PAROTID GLAND ENLARGEMENT	5	5
PATHOLOGICAL FRACTURE	1	1
PELVIC PAIN	3	3
PENIS DISORDER	2	2
PERICARDIAL EFFUSION	2	2
PERICARDITIS	1	1
PERIPHERAL EDEMA	414	415
PERIPHERAL VASCULAR DISORDER	3	4
PERSONALITY DISORDER	106	107
PETECHIA	3	3
PETECHIAL RASH	2	2
PHARYNGITIS	24	25
PHOTOPHOBIA	6	6
PHOTOSENSITIVITY REACTION	17	17
PLACENTAL DISORDER	1	1
PLEURAL DISORDER	1	1
PLEURAL EFFUSION	5	5
PNEUMONIA	35	35
POLYCYTHEMIA	3	3
POLYNEURITIS	1	1
POLYURIA	23	23
PORPHYRIA	2	2
POSTURAL HYPOTENSION	43	43
PR INTERVAL PROLONGED	1	1
PREGNANCY DISORDER	4	4
PRIAPISM	24	24
PROLACTIN INCREASED	35	35
PROSTATIC DISORDER	3	3
PROSTATIC SPECIFIC ANTIGEN INCREASE	1	1
PROTHROMBIN DECREASED <i>+1 d later</i>	11	11
PROTHROMBIN INCREASED <i>✓</i>	4	4
PRURITUS	76	76
PSEUDOMEMBRANOUS COLITIS	1	1
PSORIASIS	6	6
PSYCHOSIS	67	68
PSYCHOTIC DEPRESSION	7	7
PULMONARY EMBOLUS	15	15
PULMONARY HYPERTENSION	2	2

n=11

ZY 1946 497

OlanEvtCnt.rep

11

7/18/1999

JUL 18 1999 17:15

3175782801

PAGE.13

Zyprexa MDL 1596 Confidential-Subject to Protective Order

ZY1 00361920

Zyprexa MDL Plaintiffs' Exhibit No.01394

Page 11

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

PUPILLARY DISORDER	3	3
PURPURA	1	1
PURPURIC RASH	2	2
PUSTULAR RASH	5	5
QT INTERVAL PROLONGED	9	9
RASH	252	252
REACTION UNEVALUABLE	11	11
RECTAL HEMORRHAGE	6	6
REFLEXES DECREASED	6	6
REFLEXES INCREASED	8	8
REFRACTION DISORDER	2	2
RESPIRATORY ACIDOSIS	3	3
RESPIRATORY DISORDER	23	23
RESPIRATORY DISTRESS SYNDROME	1	1
RETINAL DISORDER	6	6
RETINAL EDEMA	1	1
RETINAL PIGMENTATION	1	1
RHABDOMYOLYSIS ✓	5	5
RHEUMATOID ARTHRITIS	1	1
RHINITIS	23	23
SALIVARY GLAND ENLARGEMENT	1	1
SARCOIDOSIS	1	1
SARCOMA	2	2
SCHIZOPHRENIC REACTION	10	10
SCREAMING SYNDROME	2	2
SEBORRHEA	2	2
SEDIMENTATION RATE INCREASED	2	2
SEPSIS	7	7
SEXUAL FUNCTION ABNORMAL	6	6
SGOT INCREASED ✓	96	96
SGPT INCREASED ✓	120	120
SHOCK	12	12
SIALADENITIS	1	1
SINUS BRADYCARDIA	2	2
SKIN DISCOLORATION	23	23
SKIN DISORDER	1	1
SKIN NODULE	2	2
SKIN STRIAE	5	5
SKIN ULCER	2	2
SLEEP DISORDER	31	31
SOMNOLENCE	684	687

OlanEvtCnt.rep

12

7/16/1999

JUL 18 1999 17:15

3175782801

PAGE.14

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

SPEECH DISORDER	117	118
SPLEEN DISORDER	1	1
SPLENOMEGALY	2	2
SPUTUM INCREASED	2	2
ST DEPRESSED	1	1
STILLBIRTH	1	1
STOMACH ATONY	1	1
STOMACH ULCER	1	1
STOMATITIS	3	3
STRABISMUS	1	1
STUPOR	56	56
SUBARACHNOID HEMORRHAGE	1	1
SUDDEN DEATH	11	11
SUDDEN INFANT DEATH	1	1
SUICIDE ATTEMPT	143	144
SUPRAVENTRICULAR TACHYCARDIA	7	7
SURGICAL PROCEDURE	1	1
SWEATING	99	99
SYNCOPE	72	72
T INVERTED	6	6
TACHYCARDIA	165	166
TARDIVE DYSKINESIA	54	54
TASTE LOSS	3	3
TASTE PERVERSION	13	13
TENDON DISORDER	2	2
TENESMUS	1	1
TENOSYNOVITIS	2	2
TESTICULAR ATROPHY	1	1
TESTIS DISORDER	2	2
THINKING ABNORMAL	140	140
THIRST	48	48
THROMBOCYTHEMIA	7	7
THROMBOCYTOPENIA	68	68
THROMBOCYTOPENIC PURPURA	2	2
THROMBOPHLEBITIS	6	6
THROMBOPLASTIN INCREASED	1	1
THROMBOSIS	6	6
THYROID DISORDER	3	3
TINNITUS	12	12
TONGUE DISCOLORATION	5	5
TONGUE DISORDER	30	30

OlanEvtCnt.rep

13

7/16/1999

JUL 18 1999 17:16

3175782801

PAGE. 15

ZY 1946 499

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

TONGUE EDEMA	29	29
TOOTH DISCOLORATION	2	2
TOOTH DISORDER	7	7
TORTICOLLIS	6	6
TOXEMIA OF PREGNANCY	1	1
TREMOR	154	155
TRISMUS	9	9
TWITCHING	89	89
ULCERATIVE COLITIS	1	1
ULCERATIVE STOMATITIS	1	1
UNEXPECTED BENEFIT	36	37
UNINTENDED PREGNANCY	55	55
URETHRAL PAIN	1	1
URINARY FREQUENCY	21	21
URINARY INCONTINENCE	85	85
URINARY RETENTION	39	39
URINARY TRACT DISORDER	7	7
URINARY TRACT INFECTION	6	6
URINARY URGENCY	6	6
URINATION IMPAIRED	8	8
URINE ABNORMALITY	17	17
UROGENITAL DISORDER	1	1
URTICARIA	32	32
UVEITIS	1	1
VAGINITIS	7	7
VASCULAR ANOMALY	2	2
VASCULITIS	2	2
VASODILATATION	24	24
VENTRICULAR EXTRASYSTOLES	4	4
VENTRICULAR FIBRILLATION	2	2
VENTRICULAR TACHYCARDIA	3	3
VERTIGO	4	4
VESICULOBULLOUS RASH	20	20
VISUAL FIELD DEFECT	1	1
VITREOUS DISORDER	2	2
VOICE ALTERATION	4	4
VOMITING	84	84
WATER INTOXICATION	6	6
WBC ABNORMAL	5	5
WEIGHT GAIN	653	653
WEIGHT LOSS	39	39

OlanEviCnt.rep

14

7/16/1999

JUL 18 1999 17:16

3175782801

PAGE.16

ZY 1946 500

for internal Lilly use only

WORKING DRAFT

Olanzapine Spontaneous Reports in Clintrace, entered through 30-Sep-1998

7,193 Unduplicated Reports in Time Period Selected

WITHDRAWAL SYNDROME	2	2
XANTHOMATOSIS	1	1

totals:

14,518

14,572

EVENT TOTAL

7,193 CASES
IN SPONTANEOUS
DATABASE FROM

9/27/96 TO
9/30/98

(PSUR-4 CUTOFF)

7,193 }
2.03
14,572

2.03 EVENTS
PER CASE

ZY 1946 501