

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1481

Case ID / Mfg #	S ex	R ace	A ge	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event								Peak Glucose Level at Time of Adverse Event			T her a py	Outcome of Hyperglycemia/ DM
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O besi ty	Weight gain while on olanzapine	Alcohol abuse / -ism; (active acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospital- ization or acidosis	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or severe hypoglycemic presentations with hospital / ICU admission or diabetic ketacidosis		
GB97082218A	m	u	u	u	Diabetic acidosis, Leukocytosis, Fever, Hypertonia	y/1 week	n	n	u	u	u	u	u	u	-	-	y; u	i	Unknown- off olanzapine
US97021057A	f	u	40	Carbamazepine, Lithium, Levothyroxine sodium, Atenolol, Trazodone, Alprazolam, Spironolactone/ hydro- chlorothiazide	Asthenia, Dehydration, Hypotension, Fever, Kidney function abnormal, Diabetic coma, Hyperglycemia, Diabetic acidosis, Neuroleptic malignant syndrome	y/20 days	n	y; HgbA1c=12.3	y	u	u	u	u	Lithium, Levothyroxine sodium, Atenolol, Spironolactone/hyd- rochlorothiazide	-	-	y; 1400	i	Improved- off olanzapine; Remains on insulin
US97043244A	m	w	43	Amantadine, Chlordiazepoxide, Trazodone, Levothyroxine sodium, Lorazepam, Maalox, Lithium, Propranolol hydrochloride	Drug level increased, Schizophrenic reaction, Creatine phosphokinase increased, SGOT increased, SGPT increased, Alkaline phosphatase increased, Tremor, Agitation, Speech disorder, Hypernatremia, Fever, Diabetes insipidus, Glycosuria, Creatinine increased, Hyperglycemia, Hyperchloremia, Hyperkalemia, Hypokalemia	y/-3 months	u	u	u	u	u	u	u	Chlordiazepoxide, Levothyroxine sodium, Lithium, Propranolol hydrochloride	-	-	y; u "slightly elevated"	u	Resolved- off olanzapine
US9705085JA	m	b	16	Imipramine, Valproate semisodium Dexamphetamine sulfate	Hyperglycemia Somnolence, Creatinine increased	y/u	u	u	u	y/BMI = 37.7	u	u	u	Imipramine	-	-	y; 500	u	Unknown- off olanzapine

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ZY 1971 1482

Case ID / Mfg #	Sex	Race	Age	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event								Peak Glucose Level at Time of Adverse Event				Therapy	Outcome of Hyperglycemia/ DM
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O besi t y	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or severe hyperglycemia/ hyperosmolar state with hospital / ICU admission or diabetic ketoacidosis			
US97074243A	f	b	58	Captopril, Indapamide	Dehydration, Somnolence, Joint disorder, Neuroleptic malignant syndrome, Fever, Respiratory acidosis, Creatine phosphokinase increased, Hyperglycemia, acidosis, Leukocytosis, Malaise, Incoordination, Vomiting, Hyperventilation, Lactic dehydrogenase increased, Hyperuricemia, Hypercalcemia, BUN increased, Creatine increased, Erythrocytes abnormal, Glycosuria, Hyperphosphatemia	y/<24 days	n	y; hyperglycemia in past	n	y/BMI ≥ 40.4	u	n	u	Indapamide	-	-	y; 1600	u	Unknown- off olanzapine	
US97090511A	m	u	51	Chlorpromazine, Paracetamol, Lorazepam	Creatine phosphokinase increased, Ketosis, Albuminuria, Fever, SGPT increased, Cogwheel rigidity	y/7 days	u	u	u	u	u	u	u	Chlorpromazine	All u [No mention of hyperglycemia in record]			u	Resolved- off olanzapine	
US97121725A	f	u	46	Haloperidol, Diphendhydramine hydrochloride, Temazepam, Naproxen sodium, Carisoprodol	Neuroleptic malignant syndrome, Kidney failure, Hepatic failure, Apnea, Fever, Dyspnea, Hypotension, Coma, Hyperglycemia, Creatine phosphokinase increased, Lactic acidosis, Nausea, Vomiting	y/13 months	n	n	u	u	u	u	u	Haloperidol, Naproxen sodium	-	-	y; 1700	u	Death	

Page 10

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ZY 1971 1483

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							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	Obes- ity	Weight gain while on olanzapine	Alcohol abuse / Ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospitaliza- tion or acidosis	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presenting with hematol / ICU admission or diabetic ketoacidosis		
US98030394A	f	u	71	Warfarin sodium, Digoxin, Verapamil hydrochloride, Diazepam	Neuroleptic malignant syndrome, fever, hypertonia, atrial fibrillation, akathisia, lactic acidosis	y/u	u	u	u	u/wt = 69kg	u	u	u	n	All u [No mention of hyperglycemia in record]			u	Improved
US980910808	f	b	35	Paroxetine hydrochloride	Neuroleptic malignant syndrome, Abdominal pain, Abdomen enlarged, Fever, Hypertonia, Coma, Diabetes mellitus, Hyperglycemia	y/3 months	n	u	u	u	u	u	u	Paroxetine hydrochloride	-	-	y; 2600	u	Unknown
AU97104762A	f	w	46	Levothyroxine sodium, Procyldine, Acitrelin, Fluoxetine hydrochloride	Hyperglycemia, Constipation, Dry mouth, Hypertonia, Akathisia, Increased appetite, Flatulence, Eructation, Prolactin increased, Psoriasis	y/18 days	y	y; [not specified]	u	y/BMI = 29.7	u	u	u	Levothyroxine sodium, Fluoxetine hydrochloride	y; 227	-	-	u	Resolved- off olanzapine
AU980800145	f	u	66	u	Hyperglycemia	y/3 months	y	y; baseline glucose 149	u	u	u	u	u	u	-	y; 473	-	d,o	Unknown
CA97054522A	m	u	22	Clonazepam, Venlafaxine hydrochloride	Hyperglycemia, Polyuria, Thirst	y/20 days	u	u	u	u	u	u	u	Venlafaxine hydrochloride	-	y; 489r	-	o	Unknown
CA97110592A	m	u	25	u	Hypercholesterolemia, Hyperglycemia, Hyperlipemia	y/<6 months	u	u	u	y	u	u	u	u	u	u	u	o	Unknown
CA98030673A	t	u	u	u	Hyperglycemia	y/u	n	u	u	u	u	u	u	u	-	y; 400	-	o	Not resolved
CL97075797A	f	u	30	Clonazepam	Weight gain, Manic reaction, Increased appetite, Lack of drug effect, Somnolence, Dyspnea, Hyperglycemia, Speech disorder, Lab test abnormal	y/u	u	u	u	y; wt = 90kg	y;30-37 kg	u	u	n	-	-	y; ["1500% above normal"]	d,o	Unknown- off olanzapine
DE97082419A	m	u	51	u	Hyperglycemia	y/23 days	n	y; hyperglycemia 2 years ago	u	n/BMI = 24.5	u	u	u	u	-	y; 300f	-	u	Unknown

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ZY 1971 1484

Case ID / Mfg #	Sex	Race	Age	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event							Peak Glucose Level at Time of Adverse Event				Therapy	Outcome of Hyperglycemic/ DM	
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	Obesit y	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospitaliza tion or acidosis	b. >=300 to < 600 mg/dl without acute hospitaliza tion or acidosis	c. > 600 mg/dl and/or acute hyperglycemic presentation with hospital / ICU admission or diabetic ketacidosis			
DE97105614A	m	u	40	Lithium, Paroxetine	Hyperglycemia, Somnolence	y/2 months	n	y; hyperglycemia on clozapine	u	y/BMI = 27.8	u	u	u	Lithium, Paroxetine	-	-	y, 890	i	Resolved- off olanzapine, off insulin	
DE98014684A	m	w	36	Lithium, Zolpidem, Amitriptyline	Hyperglycemia, Abnormal vision	y/~4 months	u	u	u	u	u	u	u	Lithium, Zolpidem, Amitriptyline	-	-	y; >400	i	Resolved- off olanzapine, off insulin	
DE980600095	f	w	19	Bezafibrate	Hyperglycemia	y/4 months	u	y; hx abn GTT	u	y/BMI = 28.7	u	u	u	n	-	y, 338	-	d,o	Improved- off olanzapine, on oral agent, diet	
DE980800285	m	w	38	Chlorprothixene hydrochloride	Hyperglycemia	y/~4 months	y	y; (not specified)	u	u	u	y	u	Chlorprothixene hydrochloride	-	-	y; 700	u	Unknown- on olanzapine	
DE980800341	f	w	38	u	SGPT increased, Gamma glutamyl, transpeptidase increased, Hyperlipemia, Hyperglycemia	y/~2 months	u	y; elevated BS on other neurologic meds	u	u	u	u	u	y, 134	-	-	-	u	Unknown- on olanzapine	
ES97071102A	f	w	34	Insulin [Unknown if this was prior to event]	Hyperglycemia	y/8 days	u	u	u	n/BMI = 24.9	u	u	u	n	-	-	y; 600	i	Unknown- off olanzapine	
ES97072179A	f	u	34	Tepazepam, Insulin	Hyperglycemia	y/1-3 days	y	y; Type 1	u	u	u	u	u	n	-	y; >400	-	i	Resolved- off olanzapine, on insulin	
EWC980400445	m	w	24	u	Hyperglycemia, Asthenia, Respiratory disorder, Death	y/25 days	n	n	u	u	u	u	u	u	-	-	y; 580	u	Death	
EWC980400467	m	u	50	Atenolol, Amodarone hydrochloride, Aspirin, Fenofibrate	Hyperglycemia, Hyperlipemia	y/u	u	u	n	y	y; 20 kg	y	u	Amiodarone, Atenolol	-	y; 582f	-	o	Unknown- on olanzapine	
EWC980400486	m	w	18	u	Hyperglycemia, Confusion	y/1-2 weeks	n	n	u	u	u	u	u	Droperidol	y; 200	-	-	u	Resolved- off olanzapine	
GB97012851A	m	u	u	Lorazepam, Droperidol	Hypertension, Hyperglycemia	y/u	u	y; may have had elevated BS prior to olanzapine	u	u	u	u	u	y; 200	-	-	-	u	Unknown	
GB97045722A	m	u	u	u	Diabetes mellitus	y/u	n	n	u	u	u	u	u	u	u	u	u	u	u	Unknown
GB97062119A	m	u	62	Glibenclamide	Hyperglycemia	y/u	y	y; Type 2	u	u	u	u	u	y; 182	-	-	-	o	Unknown	

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1485

Case ID / Mfg #	S ex	R ace	A ge	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx, onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event								Peak Glucose Level at Time of Adverse Event				T hera py	Outcome of Hyperglycemic/ DM
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O bes t y	Weight gain while on olanzapine	Alcohol abuse / -sm; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospitaliza- tion or acidosis	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presentation with hospital / ICU admission or diabetic ketacidosis			
GB9709441TA	f	u	70	Insulin, Other medication nos	Hypoglycemia, Hyperglycemia, Peripheral edema, Face edema, Edema	y/u	y	y; takes insulin	u	u/wt = 59kg	u	u	u	n	-	y; 327	-	d, i	Improved- off olanzapine	
GB97110397A	f	u	70	Insulin porcine, Trimethoprim, Procyclidine, Senna, Paracetamol	Hypoglycemia, Hyperglycemia, Peripheral edema	y/27 days	y	y; takes insulin	u	u/wt = 53kg	u	u	u	n	u	u	u	i	Resolved- off olanzapine	
GB97113486A	m	u	34	Lithium	Hyperglycemia	y/~ 5 months	u	y; diabetes while on lithium	u	u/wt = 85kg	u	u	u	Lithium	-	y; 509	-	d,o	Improved- on olanzapine	
GB98024771A	m	u	60	Metformin	Hyperglycemia, Glycosuria	y/3 weeks	y	y; type 2, on oral agent	u	u	u	u	u	n	u	u	u	o	Unknown	
GB980300170	m	u	37	Orphenadrine hydrochloride	Diabetes mellitus	y/8 months	n	u	y	y/wt = 120kg	u	u	u	n	-	-	y; u	u	Unknown	
GB980400360	m	u	u	Venlafaxine hydrochloride, Amodarone	Hyperglycemia	y/u	u	u	u	u	u	u	u	u	u	u	u	u	Unknown	
GB980400361	m	u	u	Venlafaxine hydrochloride, Amodarone	Hyperglycemia	y/u	u	u	u	u	u	u	u	Venlafaxine hydrochloride, Amodarone	u	u	u	u	Unknown- on olanzapine	
GB980801220	m	u	47	Trazodone, Carbamazepine, Chlorpromazine, Isophane insulin	Hypoglycemia, Hyperglycemia	y/~ 2 years	y	y; insulin dependent	u	u	u	u	u	u	Chlorpromazine	-	-	y; u	i	Not resolved- on olanzapine
NL98025494A	f	u	66	Lithium, Paroxetine	Diabetes mellitus, Hyperglycemia, Weight gain, Asthenia, Polyuria	y/~ 2 months	n	n	n	u	y; 9-10 kg	u	u	Lithium, Paroxetine	-	y; 476 pp	-	o	Not resolved	
US98110727A	f	w	21	Paroxetine hydrochloride, Valproate semisodium, Clonazepam, Risperidone	Convulsions, Ketosis, Lung edema	y/u	u	u	u	n/BMI = 24.1	u	u	u	Paroxetine hydrochloride, Risperidone	All u [No mention of hyperglycemia in report; seizures were primary adverse event]			u	Unknown	

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1486

Case ID / Mfg #	S ex	R ace	A ge	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event								Peak Glucose Level at Time of Adverse Event			T her ap y	Outcome of Hyperglycemia/ DM
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O besi ty	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to < 300 mg/dl	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or hyperglycemic presenta- tion with hospi- tal / ICU admission or diabetic ketacidosis		
US96114288A	m	w	45	Glyburide [unknown if pre- or post-event], Valproate semisodium, Fluvastatin, Diphenhydramine hydrochloride	Hyperglycemia	y/"immediate"	u	u	u	u	u	u	u	n	-	-	y; u	o	Unknown-on olanzapine
US96123052A	f	w	46	Ensure	Hyperglycemia	y/u	u	u	u	u	u	u	u	n	-	-	y; 600f	u	Unknown
US96123673A	m	w	75	Risperidone, Paroxetine	Diabetes mellitus, Hyperglycemia	y/u	u	u	u	u	u	u	u	Risperidone, Paroxetine	-	-	y; 560	u	Unknown-off olanzapine
US96123925A	f	w	43	Carbamazepine, Ranitidine, Furosemide, Clonazepam, Venlafaxine hydrochloride, Potassium, Nadolol	Hyperglycemia	y/~ 1 month	n	u	u	y/BMI= 54.5	u	u	u	Furosemide, Venlafaxine hydrochloride, Nadolol	y; 157	-	-	u	Unknown
US96124591A	m	u	78	u	Hyperglycemia	y/2 weeks	u	u	u	u	u	u	u	u	-	-	y; 560	i	Unknown-off olanzapine
US970111171A	m	u	34	Lithium	Dehydration, Malaise, Convulsion, Hyperglycemia, Diarrhea	y/~ 2 weeks	n	u	u	u	u	u	u	Lithium	-	-	y; 1400	i	Resolved-off olanzapine, off insulin
US97012470A	m	u	65	Thiothixene, Acetylsalicylic acid, Furosemide, Digoxin, Trihexyphenidyl	Hyperglycemia	y/u	u	u	u	n	u	u	u	Thiothixene, Furosemide	-	y; 400	-	u	Unknown-improved off olanzapine. Olanzapine rechallenged
US97014858A	u	u	u	u	Hyperglycemia	y/u	n	u	u	u	u	u	u	u	y; >200f	-	-	u	Unknown-off olanzapine
US97014882A	m	w	33	Zolpidem, Potassium, Clonazepam, Indapamide, Fluvoxamine, Felodipine, Mirtazapine	Hyperglycemia, Nausea, Hypercholesterolemia	y/~5 weeks	u	u	u	y/wt = 114kg	u	u	u	Zolpidem, Indapamide, Mirtazapine	-	y; 500	-	u	Unknown
US97015026A	u	u	u	Insulin	Hyperglycemia	y/u	y	y; insulin dependent	u	u	u	u	u	n	u	u	u	i	Unknown
US97021303A	m	w	48	Glyburide, Paracetamol	Somnolence, Hyperglycemia, Emotional lability	y/11 days	y	y; Type 2	u	y/BMI= 29.7	u	u	u	n	y; 225	-	-	o	Unknown
US97022137A	m	w	17	Nefazodone, Insulin, Valproate sodium, Fluvoxamine, Benzatropine	Hyperglycemia	y/u	y	y;Type 1	u	n/BMI = 23.1	u	u	u	Fluvoxamine	-	y; 300	-	i	Unknown

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1487

Case ID / Mfg #	Sex	Race	Age	Concomitant Drugs/Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event							Peak Glucose Level at Time of Adverse Event			Therapy	Outcome of Hyperglycemia/DM	
							Known to have DM at time of adverse event	Prior Hyperglycemia/DM; Type or Tx	Fam Hx DM	Obesity	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl and/or acute hyperglycemic presentation	b. >=300 to < 600 mg/dl without acute hospitalization or acidosis	c. > 600 mg/dl and/or acute hyperglycemic presentation with hospital / ICU admission or diabetic ketoacidosis		
US97022578A	m	u	45	Chlorpromazine hydrochloride, Lorazepam, Lithium	Death, Ketosis, Hyperglycemia, Coma, Fever	y/u	n	n	u	u	u	u	u	Chlorpromazine hydrochloride, Lithium	-	-	y; 900	u	Death
US97022638A	f	u	59	Eurosemide, Amodipine besylate	Polyuria, Hyperglycemia, Thirst, Weight gain	y/u	u	y, FBS 218 prior to olanzapine	u	y	y; 9 kg	u	u	Eurosemide	-	-	y, 700	u	Unknown
US97022844A	m	u	u	Insulin	Hyperglycemia	y/u	y	y; insulin dependent	u	u	u	u	u	n	u	u	u	i	Unknown
US97024867A	m	w	49	Allopurinol, Clonazepam, Thioridazine, Glyburide, Sotalol, Labetalol hydrochloride, Potassium chloride, Bumetanide, Fluoxetine hydrochloride	Hyperglycemia	y/u	y	y; Type 2	u	y; BMI = 52.8	u	u	u	Bumetanide, Fluoxetine hydrochloride, Labetalol hydrochloride	-	y; > 300	-	d,o	Unknown
US97030154A	f	u	72	Glucagon, Haloperidol	Hyperglycemia	y/6 days	y	y	u	y/wt = 44kg	u	u	u	Glucagon, Haloperidol	-	-	y; 524	u	Unknown
US97031054A	f	u	59	Perphenazine	Anemia, Hypokalemia, Hyperglycemia, Intentional overdose	y	y	y; Type 2, on oral agents	u	y/BMI= 28.9	u	u	u	Perphenazine	u	u	u	i	Improved-on olanzapine; on insulin
US97031177A	u	u	u	u	Pancreas disorder, Hyperglycemia	y/u	u	u	u	u	u	y; elevated enzymes	u	-	-	y; u	u	Unknown	
US97031237A	m	w	54	Glipizide, Trihexyphenidyl	Hyperglycemia, Drug interaction	y/u	y	y; Type 2	u	y/BMI= 51.2	u	u	u	n	y; 230	-	-	o	Not resolved
US97031381A	f	u	42	Thiothixene, Clonazepam, Valproate semisodium	Somnolence, Hyperglycemia, Amylase increased, Pancreatitis, Fever, Sepsis, Stupor	y/2 weeks	n	n	u	u	u	y; acute	Thiothixene	-	-	y, 1672	i	Improved-off olanzapine	
US97033103A	f	w	37	Clozapine, Clonazepam, Benztrapine mesylate, Insulin	Hyperglycemia	y/< 1 month	y	y; insulin dependent	u	y/BMI= 39.3	u	u	u	Clozapine	-	y; 304	-	d,i	Unknown
US97033517A	f	u	50	Insulin	Hyperglycemia	y/< 2 months	y	y; insulin dependent	u	y/wt = 136 kg	u	u	u	n	-	y; 359	-	i	Resolved-off olanzapine; Positive rechallenge
US97034576A	m	u	u	Clonazepam, Nifedipine	Hyperglycemia	y/u	y	y; Type 2	u	u	u	u	Nifedipine	u	u	u	d	Unknown	
US97035185A	f	u	41	Erythromycin, Benztropine mesylate, Cimetidine, Hydrochloride, Pseudoephedrine	Acidosis, Dyspnea	y/u	u	u	u	u	u	u	u	Pseudoephedrine	All u [No mention of hyperglycemia in record; admitted with metabolic acidosis]	-	-	u	Unknown

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1488

Case ID / Mfg #	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event												Peak Glucose Level at Time of Adverse Event				Therapy	Outcome of Hyperglycemia/ DM	
	Sex	Race	Age	Concomitant Drugs/Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	Obesity	Weight gain while on olanzapine	Alcohol abuse /-ism; (active/ acute or by hx)	Pancreatitis or pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl	b. >=300 to < 600 mg/dl without acute hospitalization or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presentation with hospital /ICU admission or diabetic ketoacidosis		
US97035644A	t	w	79	Insulin human zinc suspension, Pravastatin sodium, Risperidone, Phenelzine sulfate, Thyroid nos	Hyperglycemia	y/u	y	y; insulin dependent	u	y/BMI= 45.6	u	u	u	Risperidone, Thyroid nos	-	y; 300's	-	i	Resolved- off olanzapine
US97041084A	t	u	21	Valproate semisodium, Trihexyphenidyl hydrochloride, Paroxetine hydrochloride, Flurazepam, Thyroid nos	Hyperglycemia	y/u	u	u	u	u	u	u	u	Paroxetine hydrochloride, Thyroid nos	-	y; 400r	-	u	Unknown- off olanzapine
US97044282A	m	u	49	Valproate semisodium, Fluoxetine hydrochloride, Insulin [unknown if pre olanzapine]	Hyperglycemia	y/u	y	y; Type 2	u	u	u	u	u	Fluoxetine hydrochloride	-	y; > 500r	-	i, o	Unknown; on oral agent
US97045234A	u	u	u	u	Hyperglycemia	u/u	y	y; u	u	u	u	u	u	u	u	u	u	u	Unknown
US97045842A	m	b	16	Benztropine mesylate, Valproate semisodium, Imipramine, Dextroamphetamine sulfate	Hyperglycemia	y/u	u	u	u	y/BMI = 75	u	u	u	Imipramine	u	u	u	i, d	Improved- off olanzapine; off insulin
US97050193A	m	u	56	Insulin human injection isophane, Digoxin, Isosorbide dinitrate	Hyperglycemia	y/1 day	y	y; insulin dependent	u	u	u	u	u	n	y, 198	-	-	i	Unknown
US97051093A	m	b	31	u	Amblyopia, Dry mouth, Diabetes mellitus	y/u	n	u	u	y/BMI = 28.1	u	y; hx	u	u	u	u	u	i	Unknown
US97052743A	m	w	50	Clozapine	Hyperglycemia, SGOT increased, SGPT increased	y/< 2 weeks	u	y; hyperglycemia on clozapine	u	u	u	u	u	Clozapine	-	y; 500	-	u	Improved- on olanzapine
US97054048A	t	w	37	Lithium, Levothyroxine sodium, Doxycycline	Diabetic acidosis, Brain edema, Kidney tubular necrosis, Coma	y/u	u	u	u	u	u	u	u	Lithium, Levothyroxine sodium	-	-	y; > 800	u	Deteriorated
US97060070A	m	u	22	Clozapine, Valproate semisodium	Diabetes mellitus, Hyperglycemia, Diabetic acidosis, Thirst, Urinary frequency, Paresthesia, Nausea and vomiting	y/ 2 days [symptoms]; 18 days [hospitalization]	n	n	u	y/BMI = 28.7	u	u	u	Clozapine	-	-	y; 1050	i	Improved
US97060994A	t	u	u	Cisapride, Insulin	Hyperglycemia, Hypoglycemia	u/u	u	u	u	u	u	u	u	Cisapride	u	u	u	u	Unknown

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1489

Case ID / Mfg #	S ex	R ace	A ge	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event							Peak Glucose Level at Time of Adverse Event				Therapy	Outcome of Hyperglycemia/ DM
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O besi ty	Weight gain while on olanzapine	Alcohol abuse / -ism; (active, acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospitaliza- tion or acidosis	b. >300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presentation with hospitalization/ICU admission or diabetic ketacidosis		
US97062497A	t	b	17	Carbamazepine, Sertraline hydrochloride	Hyperglycemia, Diabetes mellitus, Diabetic acidosis	y/~ 6-9 weeks	n	n	y	y/BMI = 35.1	u	u	u	Sertraline hydrochloride	-	-	y; 700	i	Unknown
US97062563A	m	w	45	Clonazepam	Hyperglycemia	y/u	u	u	u	n/BMI = 26.8	u	u	u	n	-	-	y; 500f	u	Unknown
US97064489A	t	u	18	u	Hyperglycemia	y/u	n	y; hyperglycemia may have been present prior to Olanzapine		u	u	u	u	u	u	u	u	d	Not resolved- on olanzapine
US97065620A	m	u	40	none	Diabetic acidosis, Hyperglycemia, Diabetes mellitus	y/u	n	n	n	y	u	u	u	n	-	-	y; 1600	i	Improved- off olanzapine; on insulin
US97070604A	t	w	60	Levothyroxine sodium, Warfarin sodium, Lithium, Ranitidine hydrochloride	Diabetic acidosis, Glaucoma, Diabetes mellitus	y/~ 5 months	n	n	n	y/BMI = 36.5	u	u	u	Levothyroxine sodium, Lithium	-	-	y; 877	i,o,d	Improved- off olanzapine; off diabetic meds
US97071846A	m	w	28	Insulin lispro, Insulin human zinc suspension	Hyperglycemia, Somnolence	y/u	y	y; Type 1	u	u	u	u	n	-	y; ~300f	-	i	Unknown	
US97072944A	u	u	u	Venlafaxine hydrochloride, Benztrapine mesylate, Amfebutamone hydrochloride	Diabetic acidosis, Brain edema, Lactic acidosis	y/u	n	u	u	u	u	u	u	Venlafaxine hydrochloride	-	-	y; 1178	i	Improved- on insulin
US97074024A	m	b	16	Sertraline	Hyperglycemia, Hypoglycemia, Epistaxis	y/1 week	n	n	n	y/BMI = 31.8	u	u	u	Sertraline	-	y; 300	-	u	Resolved- off olanzapine
US97083850A	t	u	31	u	Glycosuria, Hematuria	y/~ 1 month	n	n	u	u/wt = 56 kg	u	u	u	u	y; 116, urine glucose 2+	-	-	u	Unknown
US97084135A	m	w	35	Valproate semisodium, Clonazepam	Hyperglycemia, Polyuria, Thirst, Ketosis, Intentional overdose	y/u	n	y; borderline increased FBS before olanzapine		y	u	u	n	n	-	-	y; 1400	i	Improved- off olanzapine; on insulin
US97084138A	t	u	65	Oral diabetic agent nos, Antihypertensive Med nos	Hyperglycemia	y/u	y	y; Type 2	u	u	u	u	u	u	-	y; ~ 300	-	o	Unknown
US97091330A	t	u	38	"Speed"	Diabetes mellitus, Thirst, Hyperglycemia	u/u	u	u	u	u	u	u	u	u	-	-	y; 600	u	Unknown

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1490

Case ID / Mfg #	S ex	R ace	A ge	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event								Peak Glucose Level at Time of Adverse Event			T hera py	Outcome of Hyperglycemic DM
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O bes si t y	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute/ chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospitaliza- tion or acidosis	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presenting with hospital /ICU admission or diabetic ketacidosis		
US97091735A	m	u	72	Paroxetine hydrochloride, Lorazepam, Clonazepam	Diabetic coma, Nervousness, Manic reaction, Thirst, Somnolence, Personality disorder, Hyperglycemia	y/ ~ 2 months	n	n	n	n	n	n	u	Paroxetine hydrochloride	-	-	y; 1700	1,0	Resolved- off olanzapine; off insulin and oral agents
US97092008A	m	u	45	u	Hyperglycemia	y/u	n	y; hyperglycemia on clozapine	u	u	u	u	u	u	-	y; 400's	-	1,0	Resolved- off olanzapine
US97093184A	f	w	39	Folic acid, Famotidine, Insulin, Multivitamins nos., Levothyroxine sodium	Unintended pregnancy, Toxemia of pregnancy, Diabetes mellitus, Hypothyroidism, Liver function tests abnormal	y/u	n [gestatio nal diabetes]	u	u	y/BMI = 31.5	u	u	u	Levothyroxine sodium	u	u	u	i	Unknown
US97093754A	m	w	21	Haloperidol, Paroxetine hydrochloride	Weight gain, Diabetes mellitus, Hyperlipemia, Esophagitis, Hyperglycemia, Polyuria, Thirst, Nausea, Vomiting, Tachycardia	y/~ 5 months	n	n	n	y/BMI = 46.7	y; 16.8 kg	y; by hx 2 years ago	u	Haloperidol, Paroxetine hydrochloride	-	-	y, 475	u	Unknown
US97094222A	f	u	50	Levothyroxine sodium, Haloperidol	Diabetic acidosis, Hyperglycemia, Thinking abnormal	y/ ~ 2 months	y	y; Type 2, DKA in past	u	y/BMI = 32.9	u	u	u	Levothyroxine sodium, Haloperidol	-	-	y; 1100	1	Unknown- on insulin
US97094765A	m	u	39	Valproate semisodium, Venlafaxine hydrochloride	Hyperglycemia	y/ ~ 4 1/2 months	u	y; hyperglycemia	u	u	u	u	u	Venlafaxine hydrochloride	n; 120	-	-	u	Unknown
US97094774A	f	b	30	Valproate semisodium, Benztropine mesylate, Lorazepam, Haloperidol decanoate	Hyperglycemia	y/ 6 weeks	u	y; BS 190 prior to olanzapine	y	y/BMI = 34.1	u	u	u	Haloperidol decanoate	-	y; 379	-	u	Unknown
US97094789A	m	u	49	Valproate semisodium, Lithium, Venlafaxine hydrochloride, Buspirone hydrochloride	Hyperglycemia	y/ > 5 weeks	u	y; baseline FBS 114-158	u	u/wt 107 kg	u	y; recovering alcoholic	u	Lithium, Venlafaxine hydrochloride	-	y; 335	-	d	Unknown
US97094810A	f	b	36	u	Hyperglycemia	y/u	u	y; hyperglycemia	u	y/BMI = 43.8	u	u	u	u	u	u	u	u	Unknown

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1491

Case ID / Mfg #	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event										Peak Glucose Level at Time of Adverse Event			Therapy	Outcome of Hyperglycemia/ DM				
	Sex	Race	Age	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx, onset and/or beginning of event? / Duration	Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	Obesity	Weight gain while on olanzapine	Alcohol abuse / -ism: (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospitalization or acidosis	b. >=300 to < 600 mg/dl without acute hospitalization or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presentation with hospital/ICU admission or diabetic ketoacidosis		
US97094819A	m	w	43	Lithium carbonate, Benztpine mesylate, Tocopherol	Hyperglycemia	y/3 months	u	u	u	u/wt = 109 kg	u	u	u	Lithium carbonate	y; 260	-	-	u	Unknown
US97094828A	f	u	33	Valproate semisodium, Buspirone hydrochloride, Sertraline hydrochloride	Hyperglycemia, Liver function tests abnormal	y/ ~ 3.5 months	u	u	u	y/BMI = 51.1	u	y; hx	u	Sertraline hydrochloride	y; 209	-	-	o	Not resolved
US97094837A	f	w	43	Paroxetine hydrochloride, Valproate semisodium, Levothyroxine sodium	Hyperglycemia	y/3 weeks	u	hyperglycemia	y	u/wt = 114 kg	u	y, active	u	Paroxetine hydrochloride; Levothyroxine sodium	y; 129	-	-	u	Unknown
US97094846A	m	b	40	Fluoxetine hydrochloride, Valproate semisodium, Diphenhydramine hydrochloride	Hyperglycemia	y/1 month	n	u	u	u/wt = 105 kg	u	u	u	Fluoxetine hydrochloride	y; 227	-	-	u	Unknown
US97094852A	f	h	51	Amitriptyline, Dyazide, Estrogens conjugated	Hyperglycemia, Liver function tests abnormal	y/ 4.5 months	u	y; ADA diet consult 6 months prior to event	u	y/BMI = 39.7	u	u	u	Amitriptyline, Dyazide, Estrogens conjugated	-	y; 349	-	d	Unknown
US97101162A	f	u	33	Paroxetine hydrochloride, Valproate semisodium, Multivitamins, Norethindrone/ethinyl estradiol	Hyperglycemia, Glycosuria, Urinary Incontinence, Weight gain	y/u	u	u	u	n/BMI = 24.8	y; ~ 13-18 kg	u	u	Paroxetine hydrochloride; Norethindrone/ethinyl estradiol	y; 156f	-	-	d	Resolved- on olanzapine
US97101204A	m	w	43	Lamotrigine, Lithium, Paroxetine	Diabetes mellitus, Apnea, Weight gain	y/ 6 months	n	n	n	y/wt = 95 kg	y; 11.3 kg	u	u	Lamotrigine, Lithium, Paroxetine	-	-	y; 567	i,o	Not resolved- off olanzapine; on oral agent
US97102155A	f	w	42	Valproate semisodium	Diabetic acidosis, Diabetes mellitus, Weight gain, Abdominal pain, Infection fungal	y/ ~ 6 months	n	n	y	y/BMI = 37.1	y; 32.3 kg	u	u	n	-	-	y; 1274	i	Improved- off olanzapine; on insulin
US97102230A	m	w	47	Carbamazepine, Clonazepam	Diabetes mellitus, Weight gain, Lack of drug effect	y/ 5 weeks	n	n	y	y/wt = 142 kg	y; 13.6 kg	u	u	n	-	-	y; 878	i,o	Not resolved- off olanzapine Positive rechallenge; on insulin
US97103109A	u	u	u	u	Diabetes mellitus	u	u	u	u	u	u	u	u	u	u	u	u	u	Unknown
US97103183A	u	u	u	u	Diabetes mellitus	u	u	u	u	u	u	u	u	u	u	u	u	u	Unknown
US97103229A	u	u	u	u	Diabetes mellitus	u	u	u	u	u	u	u	u	u	u	u	u	u	Unknown

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

Case ID / Mfg #	S ex	R ace	A ge	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event							Peak Glucose Level at Time of Adverse Event			T hera py	Outcome of Hyperglycemia/ DM		
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O besi ty	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospital- ization or acidosis	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presentation with hospital / ICU admission or diabetic ketacidosis			
US97104639A	f	w	73	Levothyroxine sodium, Loratadine, Acetbutolol, Glyburide [unknown start date]	Hyperglycemia	y/4 months	u	u; baseline glucose 165	u	u	u	u	u	Levothyroxine sodium, Acebutolol	y; 250	-	-	o	Unknown	
US97105545A	f	u	24	Sertraline hydrochloride, Valproate semisodium	Diabetic acidosis	y/u	u	u	n/BMI = 21.4	u	u	u	u	Sertraline hydrochloride	-	-	y;u	u	Unknown	
US97105839A	m	h	40	Metformin hydrochloride	Gamma glutamyl Transpeptidase increased, Hyperglycemia, Hyperlipemia	y/u	y	y; Type 2	u	n/BMI = 22.1	u	u	u	n	-	y; 352	-	o	Unknown	
US97106181A	m	u	45	Valproate semisodium	Pancreas disorder, Urinary tract disorder, Hepatomegaly, Diabetes mellitus, Abnormal vision, Confusion, Urinary frequency, Insomnia, Weight loss, Agitation, Amnesia, Thirst	y/6 weeks	n	u	u	y/BMI = 29.7	u	u	y; by hx	n	-	-	y; 1291	i, d	Improved- off olanzapine; on insulin	
US97106718A	m	w	44	Valproate semisodium	Diabetes mellitus, Hyperglycemia, Thirst, Urinary incontinence, Drug interaction	y/3 months	n	u	y	u	u	u	u	n	-	-	y; 936	o	Improved- on olanzapine; on oral agent	
US97110301A	f	u	u	Insulin	Hyperglycemia	y/u	y	y; insulin dependent	u	u	u	u	u	n	u	u	u	i	Unknown [pt has liver cancer]	
US97112197A	f	w	42	Thyroid medication nos	Hyperglycemia	y/"few weeks"	n	n	u	y/BMI = 51.1	n	u	u	Thyroid medication nos	-	-	y, 600	o	Improved- on olanzapine; on oral agent	
US97112521A	m	u	35	u	Hyperglycemia	y/u	n	u	y	y	u	u	u	u	-	-	y/u	u	Death	
US97113046A	f	b	37	u	Diabetic acidosis, Hyperglycemia, Thirst, Urinary frequency, Nausea, Vomiting, Anorexia	y/u	n	n	y	y	u	n	n	u	-	-	y; 675	i	Improved- off olanzapine; on insulin	
US97113076A	m	w	38	u	Diabetic acidosis	y/u	u	u	u	u	u	u	u	u	-	-	y;u	u	Unknown	
US97113571A	m	b	48	u	SGOT increased, Diabetes mellitus, SGPT increased	y/u	n	u	u	y/BMI = 31.5	u	y, by hx	u	u	u	u	u	u	o?	Unknown- on olanzapine

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1493

Case ID / Mfg #	S e x	R a c e	A g e	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event								Peak Glucose Level at Time of Adverse Event			T h e r a p y	Outcome of Hyperglycemia/ DM
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O bes ity	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospital- ization or acidosis	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or hyperglycemic presentation with hospital / ICU admission or diabetic ketacidosis		
US97114372A	m	b	62	Lorazepam	Hyperglycemia, Delirium, Diabetes mellitus	y/ 3-4 months	n	u	u	y	u	u	u	n	-	-	y; 700	i	Improved- on olanzapine; on insulin
US97121564A	m	b	50	u	Hyperglycemia, Intentional overdose, Weight gain, Vomiting, Malaise	y/u	n	n	n	u	y; 9.1 kg	u	u	u	-	-	y; 700's	i	Improved- on olanzapine; on insulin
US97122227A	m	u	u	u	Hyperglycemia	y/ 2 months	n	u	y	u	u	u	u	u	-	y; 331	-	o Improved- off olanzapine	
US97122539A	m	u	u	Metformin hydrochloride	Hyperglycemia	y/u	y	y, Type 2	u	n	n	u	u	n	u	u	u	o Unknown- off olanzapine	
US97122542A	m	u	u	Glipizide	Hyperglycemia	y/u	y	y; Type 2	u	u	u	u	u	n	u	u	u	i, o Unknown- off olanzapine; on insulin and oral agent	
US97122551A	f	u	u	u	Diabetes mellitus	y/ 1 year	n	u	u	u	u	u	u	u	u	u	u	o Unknown	
US97122520A	f	u	u	u	Diabetes mellitus	y/ 1 year	n	u	u	u	u	u	u	u	u	u	u	o Unknown	
US97122553A	m	u	u	u	Diabetes mellitus	y/ 1 year	n	u	u	u	u	u	u	u	u	u	u	o Unknown	
US97122562A	m	u	u	u	Diabetes mellitus	y/ 1 year	n	u	u	u	u	u	u	u	u	u	u	o Unknown	
US97122565A	f	u	u	u	Diabetes mellitus	y/ 1 year	n	u	u	u	u	u	u	u	u	u	u	o Unknown	
US98010142A	f	b	35	Stavudine, Lamivudine, Fluconazole	Acidosis, Nausea, Vomiting, Abdominal pain, Heart arrest	y/u	u	u	u	y/BMI = 47.2	u	u	u	Lamivudine	-	-	u [No mention of hyperglycemia as etiology of metabolic acidosis. Fatal cases of lactic acidosis have been reported with the use of stavudine]	u	Death

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1494

Case ID / Mfg #	S ex	R ace	A ge	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of symptom onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event								Peak Glucose Level at Time of Adverse Event				T hera py	Outcome of Hyperglycemia/ DM
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O bes ity	Weight gain while on olanzapine	Alcohol abuse / -ism; (active acute or by hx)	Pancreatitis or pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to < 300 mg/dl	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl including hyperglycemic presentation with hospital / ICU admission or diabetic ketacidosis			
US98011711A	m	w	14	Fluoxetine hydrochloride, Imipramine	Hyperglycemia, Hyperlipidemia, High density lipoprotein decreased, Alkaline phosphatase increased, Lactic dehydrogenase increased, SGOT increased, Creatinine increased, Liver fatty deposit, Hostility	y/u	u	u	u	n/BMI = 26.8	u	u	u	Fluoxetine hydrochloride, Imipramine	u	u	u	u	u	Unknown
US98012011A	m	b	40	u	Hyperglycemia	y/ < 2 months	n	u	y	n/BMI = 22.7	u	u	u	u	-	y; > 500	-	i	Improved- off olanzapine; on insulin	
US98014270A	m	w	56	u	Diabetes mellitus	y/ 3 months	u	y; hyperglycemia on Sertindole	n	y/ ~ 25% over ideal body weight	n	u	u	u	u	u	u	u	o	Improved- on olanzapine; on oral agent
US98014381A	m	b	38	u	Diabetes mellitus, Weight gain	y/ 3 months	n	u	y	y/50% over ideal body weight	y; 5 kg	u	n	u	u	u	u	u	o	Improved- on oral agent
US98015059A	m	w	32	Valproate semisodium, Buspirone hydrochloride	Diabetic acidosis, Hyperglycemia, Diabetes mellitus, Polyuria, Thirst, Abdominal pain, Nausea, Vomiting, Tachycardia, Somnolence, Stupor	y/u	n	u	y	u/wt = 66 kg	u	u	u	n	-	-	y; 404	i	Improved- on olanzapine; on insulin	
US98015350A	m	w	12	Clonidine, Salbutamol, Valproate sodium	Diabetes mellitus	y/ ~ 1 month	n	u	u	n/BMI = 23.9	u	u	u	Clonidine, Salbutamol	-	y; 556	-	i	Improved- off olanzapine; on insulin	
US98015512A	f	w	59	Amlodipine, Valproate semisodium	Glucose tolerance decreased	y/u	u	y	u	u	u	u	u	u	u	u	u	u	u	Unknown

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1495

Case ID / Mfg #	S ex	R ace	A ge	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event							Peak Glucose Level at Time of Adverse Event			T he rap y	Outcome of Hyperglycemia/ DM		
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O besi ty	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (active/ chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospitaliza tion or acidosis	b. >=300 to < 600 mg/dl without acute hospitaliza tion or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presenting with hospital / ICU admission or diabetic ketacidosis			
US98022098A	f	u	40	Thiothixene, Valproate semisodium, Paroxetine hydrochloride	Hyperglycemia, Polyuria, Thirst	n/off for 2 weeks prior to event	u	u	u	u	u	u	u	Thiothixene, Paroxetine hydrochloride	-	-	y; 800	i, d	Improved- off olanzapine; off insulin	
US98022484A	f	as	50	Paroxetine hydrochloride, Metoprolol succinate, Other medications NOS	Diabetes mellitus, Hyperglycemia	y/ 11 months	u	u	y	y/BMI = 28.1	u	u	u	Paroxetine hydrochloride, Metoprolol succinate	-	-	y; 1000	o	Improved- on olanzapine, on oral agents	
US98023100A	f	u	54	Benztropine mesylate, Thyroid nos, Risperidone	Hyperglycemia, Hypoglycemia	y/ < 1 months	y	y; Type 2 on insulin	u	n/BMI = 23.8	u	u	u	Thyroid nos, Risperidone	u	u	u	i	Unknown	
US98023517A	f	w	65	Haloperidol	Diabetes mellitus	y/2-3 months	n	n	u	y/BMI = 30.1	u	u	u	Haloperidol	-	y; 300	-	u	Unknown	
US98024165A	f	u	32	Valproate semisodium, Lithium carbonate, Lorazepam	Hemorrhagic pancreatitis, Ketosis, Fever, Gastrointestinal disorder	y/~2.5-3 months	u	u	u	u	n	y; acute hemorrhagic	Lithium carbonate	All u [No mention of hyperglycemia as etiology of ketoacidosis]	-	-	-	u	Death	
US98025323A	m	m	38	Valproate semisodium, Lithium	Diabetes mellitus, Diabetic acidosis, Hyperglycemia, Urinary incontinence, Kidney function abnormal, Tremor, Vomiting, Amnesia, Paresthesia, Abdominal pain, Myasthenia, Polyuria, Amblyopia	y/~2 months	Both u: [Initially reported to have borderline diabetes but this was later denied]	y?	y/BMI = 35.6	u	y	u	Lithium	-	-	-	y; 1825	i	Not resolved- off olanzapine; on insulin	
US98030005	m	w	72	Fluphenazine, Amitriptyline, Triamterene	Hyperglycemia, Vertigo, Hypotension	y/19 days	n	n [HgbA1c reported to be very high, raising possibility that hyperglycemia existed prior to olanzapine therapy]	u	n/BMI = 26.6	u	u	u	Fluphenazine, Amitriptyline, Triamterene	-	-	-	y; 864	i	Unknown- off olanzapine

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1496

Case ID / Mfg #	Sex	Race	Age	Concomitant Drugs/Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event							Peak Glucose Level at Time of Adverse Event				Therapy	Outcome of Hyperglycemia/ DM	
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	Obesity	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl	b. >=300 to < 600 mg/dl without acute hospitalization or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presentation with hospital / ICU admission or diabetic ketoacidosis			
US980300059	m	w	21	Valproate semisodium, Fluoxetine hydrochloride	Hyperglycemia, Intentional overdose, Ketosis, Diabetes mellitus, Polyuria, Thirst, Nausea, Vomiting	y/u	n	n	n	y/BMI = 38.1	n	u	u	Fluoxetine hydrochloride	-	-	y; 851	i	Not resolved- off olanzapine; on insulin	
US980300072	f	b	52	Valproate semisodium, Benztropine mesylate, Temazepam, Vitamin E, Estrogens conjugated	Diabetic acidosis, Diabetes mellitus, Weight gain, Lack of drug effect, Polyuria, Thirst, Hyperglycemia, Drug level decreased	y/~3 months	u	u	u	y/wt = 136kg	y; 20.4kg	u	u	Estrogens conjugated	-	-	y; 400	i	Not resolved- on olanzapine, on insulin	
US980300548	f	b	26	u	Metroorrhagia, Amenorrhea, Dysmenorrhea, Prolactin increased, Hyperglycemia, Weight gain	y/u	u	u	[possibly]	y/BMI = 46.4	y	u	u	u	u	u	u	u	u	Unknown
US980300698	m	u	40	AZT, Lamivudine, Iron, Chlorpromazine hydrochloride	Anemia, Hyperglycemia	y/~2 months	u	u	u	n/BMI = 24.4	u	u	u	Lamivudine, Chlorpromazine hydrochloride	-	y; 336	-	i	Unknown	
US980300813	f	u	30	Amoxicillin	Hyperglycemia	y/~2 months	u	u	u	u	u	u	u	n	-	y; 360r	-	u	Unknown	
US980300886	f	b	54	Phenytoin sodium, Chlorpromazine hydrochloride	Diabetes mellitus	y/<4 months	n	u	u	u/[over weight by hx]	u	u	u	Phenytoin sodium, Chlorpromazine hydrochloride	u	u	u	o	Unknown	
US980401826	f	b	11	Valproate semisodium, Amoxicillin	Diabetes mellitus, Hypoglycemia, Hyperglycemia	y/5 months	u	u	u	y/BMI = 44.1	u	u	u	n	y; 249 pp (2 hours)	-	-	o	Unknown- off olanzapine	
US980401894	f	b	34	Trazodone, Haloperidol decanoate	Diabetic acidosis, Hyperglycemia, Ketosis, Polyuria, Thirst, Abdominal pain, Nausea and vomiting, Hypotension	y/~3 months	n	n	y	n/BMI = 21.1	u	u	u	Haloperidol decanoate	-	-	y; 478	u	Unknown	
US980402030	f	w	40	none	Diabetic acidosis, Hyperglycemia, Diabetes mellitus	y/18 months	n	n	n	y/BMI = 29.7	u	u	u	n	-	-	y; 1000	i	Not resolved- off olanzapine; on insulin	

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

Case ID / Mfg #	S ex	R ace	A ge	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of ex. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event								Peak Glucose Level at Time of Adverse Event			T hera py	Outcome of Hyperglycemia/ DM	
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O besi ty	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to < 300 mg/dl without acute hospital- ization or acidosis	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presentation with hospital / ICU admission or diabetic ketacidosis			
US980402205	f	b	40	Valproate semisodium	Pulmonary embolus, Thrombosis, Diabetes mellitus	y/~2.5 months	u	y; hyperglycemia in past	n	n/BMI = 26.3	u	u	u	n	u	u	u	[Already in hospital for DVT and PE]	o	Not resolved- on olanzapine; on oral agent
US980402277	f	w	31	Protriptyline hydrochloride, Progesterone	Intentional overdose, Hyperglycemia, Somnolence, Weight loss	y/u	u	y; hx "borderline diabetes	u	y/BMI = 63	n	u	u	Protriptyline hydrochloride, Progesterone	-	y; 360	-	o	Improved- on olanzapine; on oral agent	
US980402314	f	b	35	Warfarin sodium, Heparin	Thrombosis, Diabetes mellitus	u	u	u	u	y/BMI = 31.6	u	u	u	Heparin	u	u	u	i	Unknown- on olanzapine	
US980402357	f	w	57	Valproate semisodium	Hyperglycemia, Confusion, Hormone level altered, Alkaline phosphatase increased, SGOT increased	y/~1 month	n	n	n	n/BMI = 25.9	u	u	u	n	-	-	y; 1100	i, o	Improved- off olanzapine	
US980402426	m	w	40	Valproate semisodium, Haloperidol, Lorazepam, Levothyroxine sodium, Antihypertensive medica- tions nos	Hyperglycemia	y/u	n	n	u	u	u	u	u	Haloperidol, Levothyroxine sodium	u	u	u	u	Unknown	
US980402452	m	u	35	u	Hyperglycemia	y/3-4 months	u	y; FBS 138 prior to olanzapine	u	n	n	u	u	u	-	y; 300	-	u	Unknown	
US980502976	m	w	40	Carbamazepine, Lamotrigine, Nifedipine, Lisinopril, Levothyroxine sodium	Diabetic acidosis, Hyponatremia, Polyuria, Thirst, Tachycardia, Somnolence, Confusion	y/6 weeks	n	n	u	y/BMI = 33.1	n	u	u	Lamotrigene, Lisinopril, Levothyroxine sodium, Nifedipine	-	-	y; 1356	i	Improved- off olanzapine; on insulin	
US980503031	m	w	u	Sertraline hydrochloride	Ketosis, Hyperglycemia, Diabetes mellitus	y/7-8 weeks	n	n	y	n/BMI = 20.3	u	u	u	Sertraline hydrochloride	-	-	y; 860	i	Improved- off olanzapine; on insulin	
US980503296	f	w	60	Glipizide, Sertraline hydrochloride	Hyperglycemia	y/7 months	y	y	u	u	u	u	u	Sertraline hydrochloride	u	u	u	o	Not resolved- on olanzapine; on oral agents	

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1498

Case ID / Mfg #					Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event								Peak Glucose Level at Time of Adverse Event			T her a py	Outcome of Hyperglycemia/ DM	
	S ex	R ace	A ge	Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O bes ity	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl and/or severe hyperglycemic presentation with hospital / ICU admission or diabetic ketacidosis	b. >=300 to < 600 mg/dl without acute hospital- ization or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presentation with hospital / ICU admission or diabetic ketacidosis							
US980503937	f	u	41		Thiothixene, Valproic acid, Paroxetine, Medroxyprogesterone	Hyperglycemia, Ketosis, Hyponaesthesia, Somnolence, Peripheral edema, Urinary tract infection, Glycosuria, Thirst, Polyuria, Dysuria, Weight loss, Asthenia, Dehydration	y/-7-8 months [Pt still on olanzapine when symptoms began but was off olanzapine for 2 weeks prior to diagnosis]	n	n	n	y	n	u	u	Thiothixene, Paroxetine, Medroxyprogesterone	-	-	-	y; 766	i,o	Resolved- off olanzapine; off insulin and oral agents
US980503939	f	u	40		OTC cold elixir nos	Diabetic acidosis, Pancreatitis, Somnolence, Cough increased, Weight gain	y/17 months	n	n	n	u	y; 4.5-6.8kg	u	y; acute	u	-	-	-	y; 1160	i	Resolved- off olanzapine; off insulin
US980503940	m	w	39		Lithium, Valproic acid, Hydrochlorothiazide, Triamterene, Lisinopril, Levothyroxine, Atorvastatin, Lorazepam	Hyperglycemia, Thirst, Polyuria, Amblyopia	y/-3-3.5 months	n	y; hx of glucose 217	u	y/BMI = 39.1	n	u	u	Lithium, Hydrochlorothiazide, Triamterene, Lisinopril, Levothyroxine, Atorvastatin	-	-	-	y; 686	d,o	Improved- off olanzapine; on oral agent
US980503942	m	w	38		Sertraline hydrochloride	Hyperglycemia, Sexual function abnormal, Polyuria, Thirst, Amblyopia	y/u	n	n	u	y/wt = 105kg	u	u	u	Sertraline hydrochloride	-	y; 372f	-	d	Unknown- off olanzapine	
US980604695	m	w	40		Lithium carbonate, Diazepam, Carbamazepine, Trazodone, Nefazodone hydrochloride, Paroxetine hydrochloride, Hydroxyzine pamoate, Gemfibrozil	Hyperglycemia, Diabetes mellitus	y/-7 months	u	y; hyperglycemia 5 months prior to olanzapine	u	y/BMI = 30	u	u	u	Lithium carbonate, Paroxetine hydrochloride	-	-	-	y; 1453	u	Unknown- off olanzapine
US980605251	m	w	44		Lithium, Valproate semisodium, Niacin, Gemfibrozil	Hypercholesterolemia, Hyperlipemia, Hyperglycemia, Intentional overdose	y/u	n	n	u	y/BMI = 36.9	u	u	u	Lithium	u	u	u	u	u	Unknown- off olanzapine
US980605305	m	u	55			Hyperlipemia, Hyperglycemia	y/-5 months	u	u	u	u	u	u	u	u	-	y; > 400	-	u	u	Unknown
US980605500	m	u	40		u	Hyperglycemia	y/u	n	y; reported to have NIDDM "traits"	u	u	u	u	u	u	y; 202r	-	-	-	u	Unknown- off olanzapine

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1499

Case ID / Mfg #	Sex	Race	Age	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event							Peak Glucose Level at Time of Adverse Event			Therapy	Outcome of Hyperglycemia/ DM	
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O b s i t y	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospitaliza- tion or acidosis	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presenting with hospital / ICU admission or diabetic ketacidosis		
US980605511	m	b	30	Glipizide	Hyperglycemia, Intentional overdose	y/-6 months	y	y; Type 2	u	u	u	u	u	n	-	y; 300r	-	o	Improved- on oral agents
US980605522	f	u	60	Glyburide	Hyperglycemia	y/u	y	y, Type 2	u	y	u	u	u	n	-	y; 400r	-	o	Unknown- on oral agents
US980605536	m	u	29	Insulin	Hyperglycemia	y/u	y	y; takes insulin	u	u	u	u	u	n	u	u	u	i,o	Resolved- off olanzapine; on insulin and oral agent
US980605848	m	b	36	u	Hyperglycemia, Nausea, Somnolence	y/3 months	n	n	u	u	u	u	u	u	-	-	y; 800	u	Resolved- off olanzapine
US980606134	m	u	25	none	Diabetic acidosis, Diabetes mellitus	y/-3 months	u	u	u	u	u	u	u	n	-	-	y; u	i	Not resolved- off olanzapine; on insulin
US980606177	m	na	42	Trifluoperazine hydrochloride, Buspirone hydrochloride, Procyclidine hydrochloride	Hyperglycemia, Weight loss, Polyuria, Thirst	y/*few weeks*	u	u	n	y/BMI \leq 28.1	n	u	u	Trifluoperazine hydrochloride	-	y; 500	-	u	Resolved- off olanzapine [later dx'd with Type 2 diabetes]
US980706297	m	b	38	Thiazide nos, Calcium channel blocker nos	Hyperglycemia	y/13 days	n	n	u	y/BMI \leq 36.5	u	u	u	Thiazide nos, Calcium channel blocker nos	-	y, 380	-	o	Resolved- off olanzapine; off oral agent
US980707440	f	w	17	Sulfamethoxazole, Clonazepam, Vitamin supplement NOS, Human NPV inst., Propr. Fluoxetine hydrochloride, Dietary supplement	Hyperglycemia	y/u	y	y; Type 1	y	n/BMI $= 25.8$	u	u	u	Fluoxetine hydrochloride	y; 250	-	-	i	Unknown
US980707664	f	b	34	Paroxetine hydrochloride	Hyperglycemia, Weight gain, Hostility	n/hyperglycemia detected 11 days after olanzapine discontinuation	u	u	u	u/wt = 88kg	y	u	u	Paroxetine hydrochloride	-	y; 400	-	i	Unknown- off olanzapine
US980707694	m	u	37	Bupropion, Dextroamphetamine sulfate, Diphenhydramine, Methylprednisolone	Allergic reaction, Maculopapular rash, Pruritus, Tachycardia, Hypertension, Face edema, Rash, Hyperglycemia, Leukocytosis, Hormone level altered	y/u	u	u	u	Methylprednisolone	y, 191 [increased glucose attributed to steroids]	-	-	-	-	u	Unknown- off olanzapine		

Page 27

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1500

Case ID / Mfg #	S ex	R ace	A ge	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event							Peak Glucose Level at Time of Adverse Event			Therapy	Outcome of Hyperglycemia/ DM	
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O besi ty	Weight gain while on olanzapine	Alcohol abuse (-ism; acute or by hx)	Pancreatitis or other pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl without acute hospitali- zation or acidosis	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presentation with hospital, ICU admission or diabetic ketacidosis		
US980807835	m	b	49	Valproate sodium, Fluphenazine hydrochloride	Hyperglycemia, Intentional overdose, Somnolence, Tongue edema, Speech disorder, 130 beats/minute,	y/7.5 months	n	n	u	y/BMI = 32.8	u	u	u	Fluphenazine hydrochloride	-	-	y; 1200	i	Resolved- off olanzapine
US980808531	m	u	53	none	Hyperglycemia	y/~1.5 months	n	y; hx borderline hyperglycemia	u	n/BMI = 23.8	u	u	u	n	-	y; 331	-	o	Resolved- off olanzapine; off oral agents
US980808526	t	w	17	Sulfamethoxazole, Clonazepam, Human insulin, Lispro, Fluoxetine hydrochloride	Hyperglycemia, Cystitis	y/u	y	y; Type 1	u	n/BMI = 25.8	u	u	u	Fluoxetine hydrochloride	y; 250	-	-	i	Unknown
US980808919	t	w	26	Prenatal vitamins, Dihydroxyaluminum sodium carbonate	Diabetes mellitus	y/u	y; gestatio nal diabetes	u	u	y/BMI = 30.1	u	u	u	n	u	u	u	u	Unknown
US980808998	m	b	49	Clonazepam, Haloperidol, Diphenhydramine hydrochloride, Enalapril maleate, Nifedipine, Oral hypoglycemic agent NOS	Hyperglycemia	y/3 months	y	y; Type 2	u	u/wt = 109kg	u	u	u	Haloperidol, Enalapril maleate, Nifedipine	-	y; 406f	-	i,o	Resolved- off olanzapine; off insulin
US980909488	m	w	52	Paroxetine hydrochloride	Liver function tests abnormal, Diabetes mellitus, Gamma glutamyl transpeptidase increased, Alkaline phosphatase increased, Bilirubinemia	y/~6 months	u	u	u	y/BMI = 36.7	u	u	u	Paroxetine hydrochloride	-	y; 417	-	o	Unknown- on olanzapine
US980909512	m	u	50	u	Diabetic acidosis, Hyperglycemia, Somnolence, Tongue edema, Speech disorder, Intentional	y/~8 months	u	u	u	u/wt = 102kg	u	u	u	u	-	-	y; 1200	i	Resolved- off olanzapine

Review of Commercially Marketed (Spontaneous) Olanzapine Hyperglycemic Adverse Event Reports

ZY 1971 1501

Case ID / Mfg #	S ex	R ace	A ge	Concomitant Drugs/ Prescription Medications as symptoms developed	COSTART Terms	On olanzapine @ time of sx. onset and/or beginning of event? / Duration	Risk Factors / Clinical Conditions for Hyperglycemia/Diabetes Mellitus which Pre-existed Adverse Clinical Event							Peak Glucose Level at Time of Adverse Event			T hera py	Outcome of Hyperglycemia/ DM			
							Known to have DM at time of adverse event	Prior Hyperglycemia/ DM; Type or Tx	Fam Hx DM	O bes ity	Weight gain while on olanzapine	Alcohol abuse / -ism; (active/ acute or by hx)	Pancreatitis or pancreatic dysfunction (acute, chronic or by hx)	Taking drug(s) reported to elevate glucose/ cause DM	a. >126 to <300 mg/dl	b. >=300 to < 600 mg/dl without acute hospitaliza- tion or acidosis	c. > 600 mg/dl and/or severe hyperglycemic presentation with hospital / ICU admission or diabetic ketacidosis				
US980909827	m	b	42	Ranitidine hydrochloride, Doxepin, Salbutamol inhaler	Diabetes mellitus, Albuminuria, Polyuria, Thirst, Tachycardia, Weight loss	y/~4.5 months	u	u	y	n/BMI = 26.7	n	u; social drinker	u	Doxepin, Salbutamol inhaler	-	-	y; 796	i,o	Improved- on olanzapine, on insulin and oral agents		
US980910148	f	w	39	Valproate sodium	Diabetic acidosis	y/~1 month	[contradi- ctory report]	y; gestational diabetes	y	y/wt = 115kg	u	u	u	n	-	-	y; 516	i	Resolved- off olanzapine		
US980910237	m	b	54	Lithium carbonate	Hyperglycemia, Confusion	y/u	u	u	u	y/BMI = 39.7	u	u	u	Lithium carbonate	-	-	y; 800	i	Resolved- off olanzapine; off insulin		
US980910306	f	w	18	u	Hyperglycemia	y<1 month	u	u	y	y/BMI = 33.5	u	u	u	u	u	u	u	o	Unknown		
US980910817	m	b	38	none	Diabetic acidosis, Hyperglycemia, Leukocytosis	y/12 days	u	u	n	y/BMI = 31.1	u	u	u	n	-	-	y; 1200	i	Unknown- off olanzapine		
US980910955	m	w	54	Mesoridazine, Metformin, Glipizide, Sertraline hydrochloride, Clonazepam, Simvastatin	Somnolence, Hyperglycemia	y/u	y	y; Type 2	u	n/BMI = 22.5	u	u	u	Sertraline hydrochloride	y; 250	-	-	o	Unknown- on olanzapine		
ZA97062884A	m	w	67	Insulin human injection Isophane, Sertraline hydrochloride, Zopiclone	Hyperglycemia	y/1 day	y	y; insulin dependent	u	u	u	u	u	Sertraline hydrochloride	u	u	u	i	Improved- on olanzapine; on insulin		
US97122359A	f	u	31	Fluvoxamine maleate, Lithium	Hyperglycemia, Thirst, Urinary frequency	y/~6 months	u	u	u	y	u	y; by hx in past	u	Fluvoxamine maleate, Lithium	u	u	u	o	Improved- on olanzapine; on oral agent		
US980402389	f	w	53	Buspirone hydrochloride, Insulin	Hyperglycemia, Hypoglycemia, Weight loss	y/u	y	y; takes insulin	u	y/BMI = 42.9	n	u	u	n	-	y; 500	u	i	Unknown		
US980707656	u	u	70	u	Lactic acidosis	y/u	u	u	u	u	u	u	u	u	u	u	u	u	[No mention of hyperglycemia]	u	Improved-off olanzapine