

## FDA REPORTED **PROZAC** ADVERSE REACTION CASES 04/10/1996

In the document below the UK SSRI site has attempted to identify adverse reactions that are life-threatening PHYSIOLOGICAL medical emergencies in **RED**, such as **cancer, heart attacks** and **strokes**. The figures for “**death**” and “**sudden death**” are also outlined in **RED** with **asterisks** added. Adverse PSYCHOLOGICAL and CNS reactions that affect the STATE OF MIND have been identified in **BLUE**. Please bear in mind that reactions such as **akathisia, agitation** and **suicidal ideation**, although classified in **blue** as ‘psychological’, may also have resulted in emergency treatment. **PINK** has been used to try to identify movement disorders such as **Tardive Dyskinesia** and including **paralysis**.

We are not medical practitioners and so may have unknowingly omitted reactions that should have been highlighted and vice versa, but hopefully the identification below will serve to sort out different types of reactions.

"FDA Statistics (Gained through the Freedom Of Information Act)

~~~~~  
FDA REPORTED PROZAC CASES; TOTAL 35,230 (1987:-1995)  
ALL FDA COSTART REACTION TERMS IN DATA ALPHABETICAL TERM ORDER -  
04/10/96 -  
~~~~~

ABDO ENLARGE 35	ANEMIA MICROCYT 3
ABDO SYND ACUTE 9	ANEMIA NORMOCYT 3
ABORTION 96	ANEMIA REFRACT 1
ABSCESS 8	ANEURYSM INTRACRAN 5
ABSCESS BREAST 2	ANGINA PECTORIS 46
ABSCESS PERIODONT 1	ANGIOEDEMA 38
ACCOMMODATION ABNORM 4	ANISOCORIA 7
ACIDOSIS 15	ANOMALY CONGEN 202
ACIDOSIS DIABET 7	ANOMALY CONGEN CNS 3
ACIDOSIS LACTIC 1	ANOMALY CONGEN MS 3
ACIDOSIS RESP 4	ANOMALY CONGEN RESP 1
ACNE 80	ANOMALY HEART 2
ADAMS STOKES SYND 2	ANOMALY VASCUL 8
<b>ADDISON CRISIS 1</b>	<b>ANOREXIA 396</b>
ADENOMA 15	ANORGASMIA 566
ADENOMA THYR 1	<b>ANTICHOLINERG SYND 12</b>
ADH INAPPROP 85	ANTICOAG DEC 2
ADREN INSUFFIC 3	ANTICOAG INC 7
<b>AGITATION 1191</b>	<b>ANTISOCIAL REACT 8</b>
AGRANULOCYTOSIS 18	ANURIA 6
<b>AKATHISIA 299</b>	<b>ANXIETY 1153</b>
AKINESIA 8	<b>APATHY 105</b>
ALBUMINURIA 25	APHASIA 27
ALCOHOL INTOLER 45	APNEA 59
ALKALOSIS 1	APPETITE INC 105
ALKALOSIS RESP 4	APPLICAT SITE REACT 4
<b>ALLERG REACT 151</b>	ARRHYTHMIA 107
ALOPECIA 696	ARRHYTHMIA ATR 3
ALTERED DRUG LEVEL 3	ARRHYTHMIA NOD 2
ALTERED HORMONE LEVE 28	ARRHYTHMIA VENT 7
ALTERED NEUROTR LEVE 8	<b>ARTERIOSCLEROSIS 18</b>
AMBLYOPIA 188	ARTERIOSPASM 1
AMENORRHEA 129	ARTERITIS 6
<b>AMNESIA 557</b>	ARTHRALGIA 479
AMYLASE INC 23	ARTHRITIS 117

ANA 93  
ANAPHYL 39  
ANEMIA 99  
**ANEMIA APLAST 14**  
ANEMIA B12 DEFIC 4  
ANEMIA FOLIC DEFIC 1  
ANEMIA HEMOL 17  
ANEMIA HEMOL DCN 1  
ANEMIA HEMOL DCP 4  
ANEMIA HEMOL ICP 1  
ANEMIA HYPOCHROM 32  
ANEMIA IRON DEFIC 12  
ANEMIA MACROCYT 4  
ANEMIA MEGALOBLAST 6  
**AV BLOCK COMP 13**  
AV BLOCK FD 6  
AV BLOCK SD 4  
**BARBITUR INTOX 2**  
BILIRUBINEM 68  
BILIRUBINURIA 1  
BIRTH PREMAT 26  
BIRTH WEIGHT SUBNORM 2  
BLEED TIME INC 44  
BLEPHARITIS 8  
**BLIND 23**  
BLIND COLOR 3  
BLIND NIGHT 2  
BLOOD DYSCRASIA 7  
BODY ODOR 11  
BONE DIS 10  
BONE FRACT SPONTAN 77  
BRADYCARDIA 133  
BRADYCARDIA SINUS 16  
**BRAIN STEM DIS 3**  
**BRAIN SYND ACUTE 45**  
BRAIN SYND CHRON 16  
BREAST ENGORGE 5  
BREAST ENLARGE 65  
BREAST FIBROCYST 26  
BRONCHIOLITIS 3  
BRONCHITIS 57  
BUCCOGLOSSAL SYND 126  
BUN INC 11  
BUNDLE BRANCH BLOCK 25  
BURSITIS 8  
CACHEXIA 8  
CAPILL FRAGIL INC 2  
**CARCINOMA 30**  
**CARCINOMA BLADDER 1**  
**CARCINOMA BREAST 22**  
**CARCINOMA CERVIX 3**  
**CARCINOMA ENDOMETR 3**  
**CARCINOMA GI 17**  
**CARCINOMA LIVER 2**  
**CARCINOMA LUNG 9**  
**CARCINOMA PROSTATE 3**  
**CARCINOMA SKIN 12**  
**CARCINOMA THYR 1**  
CARDIOMEGALY 5  
CARDIOMYOPATHY 12  
CARDIOSPASM 5  
**CARDIOVASC DIS 57**

ARTHRITIS RHEUMAT 14  
ARTHROSIS 79  
ASCITES 7  
ASPHYXIA 11  
ASTHENIA 788  
ASTHMA 97  
**ATAXIA 124**  
**ATAXIA CEREBELL 4**  
**ATELECTASIS 3**  
ATROPHY MUSCLE 2  
ATROPHY OPTIC 2  
ATROPHY SKIN 3  
ATROPHY TESTIS 4  
AV BLOCK 11  
**CEREBROVASC DIS 10**  
CERVICITIS 1  
CERVIX DIS 1  
CHEILITIS 2  
CHILLS 96  
CHILLS FEVER 39  
CHLOASMA 1  
CHOLANGITIS 3  
CHOLECYST 24  
CHOLELITH 20  
CHOLINERG SYND 1  
CHOREOATHETOSIS 15  
CHROMATOPSIA 2  
CHROMOSOME ABNORM 1  
CINCHONISM 1  
CLITORIS ENLARGE 4  
**CNS DEPRESS 11**  
**CNS STIMULAT 53**  
COAGUL DIS 25  
COAGUL TIME INC 3  
**COGWHEEL RIGID 45**  
COLITIS 34  
COLITIS HEM 2  
COLITIS PSEUDOMEM 3  
COLITIS ULCER 15  
COLLAGEN DIS 2  
**COMA 181**  
COMA DIABET 3  
COMA HEPATIC 3  
**CONFUS 591**  
CONJUNCTIVITIS 39  
CONSTIP 79  
**CONVULS 642**  
**CONVULS GRAND MAL 275**  
COOMBS DIR TEST POS 1  
COORDINAT ABNORM 118  
COR PULM 2  
CORNEAL LESION 8  
CORNEAL OPACITY 4  
**CORONARY ART DIS 22**  
COUGH INC 132  
CRAMPS LEG 25  
CREATINE PK INC 65  
CREATININE CLEAR DEC 2  
CREATININE INC 25  
CSF ABNORM 5  
CUSHINGS SYND 4  
**CYANOSIS 12**

CATARACT 43  
CATARACT NOS 1  
**CATATON REACT 36**  
CELLULITIS 12  
CEREBELL SYND 1  
**CEREBROVASC ACCID 109**  
**\*\*DEATH 121 \*\***  
DEHYDRAT 37  
**DELIRIUM 123**  
**DELUSIONS 80**  
**DEMENTIA 36**  
**DEPERSONAL 159**  
**DEPRESSION 1111**  
**DEPRESSION PSYCHOTIC 1205**  
DERM CONTACT 16  
DERM EXFOL 23  
DERM FUNG 11  
DERM LICHEN 11  
DERMATOMYOSITIS 2  
DIABETES INSIPID 1  
DIABETES MELL 25  
DIARRHEA BLOODY 26  
DIC 2  
**DIGITALIS INTOX 3**  
DIPLOPIA 42  
DISCOLOR TONGUE 22  
DISCOLOR TOOTH 6  
DIZZINESS 636  
**DREAM ABNORM 437**  
**DRUG DEPEND 90**  
**DRUG DEPEND ADDICT 35**  
**DRUG INTERACTION 733**  
DRUG LEVEL DEC 33  
DRUG LEVEL INC 265  
DRY EYE 22  
DRY MOUTH 114  
DUODENITIS 1  
DYSARTHRIA 25  
**DYSKINESIA 45**  
**DYSKINESIA TARDIVE 72**  
DYSMENORRHEA 16  
DYSpareunia 3  
DYSPEPSIA 202  
DYSPHAGIA 69  
DYSpNEA 333  
**DYSTONIA 151**  
DYSURIA 50  
EAR DIS 20  
ECCHYMOSIS 437  
**ECG ABNORM 68**  
ECZEMA 15  
EDEMA 100  
**EDEMA BRAIN 10**  
EDEMA FACE 174  
EDEMA GENERAL 46  
EDEMA INJECT SITE 1  
EDEMA LABIA 1  
**FIBRILLAT VENT 23**  
FIBRIN INC 1  
FIBRINOGEN DEC 1  
FIBRINOGEN INC 1  
CYST 43  
CYSTITIS 24  
DEAF 82  
DEAF PERM PART 2  
DEAF TRANS PART 4  
DEAF TRANS TOTAL 1  
EDEMA LARYNX 19 [FLUID ON]  
**EDEMA LUNG 48**  
EDEMA PERIPH 191  
EDEMA RETINAL 2  
EDEMA SCROTUM 1  
EDEMA TONGUE 62  
**EEG ABNORM 52**  
EFFUS PERICARD 1  
EFFUS PLEURAL 25  
EJACULAT ABNORM 281  
ELECTROLYTE ABNORM 11  
ELECTROLYTE DEPLET 2  
**EMB 5**  
**EMB CEREBR 3**  
**EMB PULM 51**  
**EMOTION LABIL 271**  
EMPHYSEMA 4  
ENCEPHALITIS 2  
ENCEPHALOP HYPERTENS 2  
ENCEPHALOPATHY 27  
ENDO DIS 4  
ENDOCARD 3  
ENDOMETR DIS 6  
ENTERITIS 2  
ENZYME ABNORM 15  
EOSINOPHILIA 42  
EPIDERM NECRO 8  
EPIDIDYMITIS 8  
EPISTAXIS 69  
ERUCTAT 12  
ERYTHEMA MULT 44  
ERYTHEMA NOD 19  
ESOPHAGITIS 55  
ESR INC 71  
EUPHORIA 110  
EXOPHTHALMOS 7  
EXTRAPYR SYND 270  
EXTRASYSTOLES 9  
EXTRASYSTOLES BIGEM 18  
EXTRASYSTOLES SUPVEN 8  
EXTRASYSTOLES VENT 50  
EYE DIS 55  
FACIES MASK 14  
FEMININE 1  
FERTIL DEC FEM 3  
FERTIL DEC MALE 13  
FERTIL INC FEM 4  
FETAL DIS 11  
FEVER 358  
FEVER MALIGNANT 13  
FIBRILLAT ATR 42  
HEALING ABNORM 4  
**HEART ARREST 96**  
**HEART BLOCK 10**  
**HEART FAIL 60**

FIBRO LUNG 39  
FIBRO MESENTER 1  
FIBRO RETROPERIT 3  
FIBRO TENDON 2  
FLATUL 80  
**FLU SYND 149**  
FLUTTER ATR 6  
**FOOT DROP 7**  
FURUNCULOSIS 7  
**GAIT ABNORM 142**  
**GANGRENE 2**  
**GANGRENE INTEST 2**  
**GANGRENE PERIPH 1**  
GASTRITIS 39  
**GASTRITIS HEM 1**  
GASTROENTERITIS 15  
GGTP INC 63  
GI DIS 124  
GINGIVITIS 26  
GLAUCOMA 34  
GLOBULIN DEC 1  
GLOBULIN INC 2  
GLOBULIN INC GAMMA 2  
GLOMERULITIS 4  
GLOSSITIS 53  
GLUCOCORT INC 4  
GLUCOSE TOLER DEC 3  
GLYCOSURIA 4  
GOITER 13  
GONADOTR DEC FSH 2  
GONADOTR DEC LH 2  
GONADOTR INC 1  
GONADOTR INC FSH 8  
GONADOTR INC LH 4  
GOUT 8  
GRANULOMA 3  
GRANULOMA SKIN 1  
GROWTH ACCELER 2  
GROWTH RETARD 2  
GUILLAIN BARRE SYND 6  
GYNECOMASTIA 26  
HAIR DIS 26  
HAIR DISCOLOR 9  
HALITOSIS 5  
**HALLUCIN 482**  
HANGOVER 9  
HDL DEC 3  
HEADACHE 1187  
HEADACHE VASC 7  
HYPERALGESIA 1  
HYPERCALCEM 9  
HYPERCHLORHYDRIA 2  
HYPERCHOLESTEREM 93  
HYPERESTHESIA 17  
HYPERGLYCEM 88  
HYPERKALEM 13  
HYPERKINESIA 202  
HYPERLIPEM 46  
HYPERNATREM 7  
HYPERPLASIA ENDOMETR 5  
HYPERTENS 407  
HYPERTENS PULM 5

**HEART FAIL LEFT 4**  
**HEART FAIL RIGHT 44**  
**HEM 81**  
**HEM CEREBR 12**  
HEM COLON 2  
HEM ESOPH 3  
HEM EYE 38  
HEM GI 66  
HEM GUM 14  
**HEM INTRACRAN 5**  
**HEM LUNG 2**  
HEM MUSCLE 2  
HEM POSTPARTUM 1  
**HEM PREGN 8**  
HEM RECTAL 34  
HEM RETINAL 18  
HEM RETROPERIT 1  
**HEM SUBARACHNOID 9**  
HEM UTER 19  
HEM VAGINAL 65  
HEMATEMESIS 15  
**HEMATOMA SUBDURAL 4**  
HEMATURIA 84  
HEMIPLEGIA 31  
HEMOCHROMATO 2  
HEMOLYSIS 3  
**HEMOPERITON 2**  
HEMOPTYSIS 19  
HEMOSIDERO 1  
HEMOTHORAX 1  
HEPATITIS 98  
HEPATITIS C 1  
HEPATITIS HBSAG 2  
HEPATOMA 2  
HEPATOMEGALY 13  
HEPATORENAL SYND 4  
HEPATOSPLENOMEGALY 2  
HERNIA 12  
HERPES SIMPLEX 30  
HERPES ZOSTER 24  
HICCUP 14  
HIRSUTISM 33  
HIV SYND 4  
HIV TEST POS 2  
**HOSTILITY 999**  
**HYDROCEPHALUS 3**  
HYDRONEPHROSIS 2  
HYPER GUM 3  
HYPERACUSIS 1  
INFECT 101  
INFECT BACT 1  
INFECT SUPER 1  
INFECT URIN TRACT 53  
INFECT VIRAL 2  
INJECT SITE REACT 1  
INJURY ACCID 307  
**INJURY INTENT 502**  
INSOMNIA 1334  
INTEST LARGE PER 2  
INTEST PER 1  
INTRACRAN HYPERTENS 11  
IRITIS 7

**HYPERTHYR 42**  
**HYPERTONIA 268**  
HYPERTROPHY 1  
HYPERTROPHY SKIN 4  
HYPERURICEM 6  
HYPERVENTIL 43  
HYPESTHESIA 50  
HYPOCALCEM 9  
HYPOCHLOREM 7  
HYPOCHOLESTEREM 4  
HYPOGLYCEM 145  
HYPOKALEM 73  
**HYPOKINESIA 40**  
HYPOMAGNESEM 1  
HYPOMENORRHEA 6  
HYPONATREM 460  
HYPOPROTEINEM 5  
HYPOTENS 146  
HYPOTENS POST 84  
**HYPOTHERMIA 18**  
HYPOTHYR 94  
HYPOTONIA 10  
HYPOVENTIL 10  
HYPOVOLEM 1  
HYPOXIA 25  
**HYSTERIA 28**  
ILEITIS 6  
ILEUS 5  
IMMUNE SYSTEM DIS 5  
IMMUNOGLOBUL INC 2  
IMPACT FECAL 1  
IMPOTENCE 243  
INCONTIN FECAL 29  
INCONTIN URIN 122  
INCREASED EFFECT 29  
**INFARCT CEREBR 14**  
**INFARCT MYOCARD 122**  
**INFARCT PULM 1**  
LIPODYSTROPHY 1  
**LIVER CIRRH 14**  
**LIVER DAMAGE 35**  
**LIVER FAIL 26**  
LIVER FATTY 20  
LIVER FUNC ABNORM 389  
LIVER TENDER 4  
LUNG DIS 41  
LUNG FUNC DEC 4  
LYMPHADENO 79  
**LYMPHEDEMA 1**  
LYMPHOCYTOSIS 8  
**LYMPHOMA LIKE REACT 15**  
MALABSORP SYND 1  
MALAISE 167  
**MANIC DEPRESS REACT 30**  
**MANIC REACT 553**  
MARROW DEPRESS 17  
MASTITIS 3  
**MED ERROR 24**  
MEGACOLON 1  
MEGAKARYO DEC 1  
MEGAKARYO INC 1

**ISCHEMIA CEREBR 20**  
**ISCHEMIA MYOCARD 12**  
JAUNDICE 56  
JAUNDICE CHOLESTAT 29  
JAUNDICE NEONAT 1  
JOINT DIS 75  
KERATITIS 5  
KERATOCONJUNCTIVITIS 7  
KETOSIS 9  
KIDNEY CALCULUS 35  
**KIDNEY FAIL ACUTE 16**  
KIDNEY FUNC ABNORM 14  
KIDNEY POLYCYSTIC 1  
KIDNEY TUBUL DIS 1  
LAB TEST ABNORM 93  
LAB TEST INTERFER 31  
LABOR ABNORM 22  
LACRIMATION DIS 18  
LACTATION DEC 1  
LACTATION FEM 269  
LACTATION MALE 3  
LARYNGISMUS 36  
LARYNGITIS 10  
LDH INC 50  
LE SYND 70  
LE TEST ABNORM 4  
**LEUKEMIA 6**  
**LEUKEMIA ACUTE 5**  
**LEUKEMIA ACUTE LYMPH 2**  
**LEUKEMIA ACUTE MYELO 1**  
LEUKOCYTOSIS 81  
LEUKODERMA 8  
LEUKOPENIA 191  
LEUKOPLAKIA ORAL 2  
LEUKORRHEA 9  
LIBIDO DEC 677  
LIBIDO INC 102  
LIPASE INC 1  
**MYOPATHY 20**  
MYOSITIS 28  
NAIL DIS 22  
NASAL SEPTUM DIS 1  
NAUSEA 971  
NAUSEA VOMIT 248  
NAUSEA VOMIT DIAR 40  
NECK RIGID 39  
**NECRO 2**  
**NECRO BONE 13**  
**NECRO INTEST 4**  
**NECRO KIDNEY PAPILL 1**  
**NECRO KIDNEY TUBUL 2**  
**NECRO LIVER 8**  
**NECRO SKIN 2**  
**NEOPL 18**  
**NEOPL BLADDER 5**  
**NEOPL BREAST 11**  
**NEOPL CNS 7**  
**NEOPL LARYNX 1**  
**NEOPL SKIN 8**  
**NEOPL THYR 1**  
**NEOPL UTER 1**

**MELANOMA SKIN 4**

MELANOSIS 3

MELENA 23

MENINGISM 2

**MENINGITIS 5**

MENOPAUSE 15

MENORRHAGIA 69

MENS DIS 110

**MENTAL RETARD 4**

METHEMOGLOBIN 1

METRORRHAGIA 111

MIGRAINE 108

MIOSIS 1

MONILIA 4

MONILIA GI 2

MONILIA ORAL 6

MONILIA SKIN 1

MONILIA VAGINA 3

MONOCYTOSIS 2

MONOPLÉGIA 1

**MOVEMENT DIS 59**

MUCOUS MEM DIS 6

MYALGIA 266

**MYASTHENIA 72**

MYDRIASIS 66

MYELOFIBROSIS 2

**MYELOMA 1**

MYELOPROLIF DIS 1

MYOCARDITIS 2

**MYOCLONUS 163**

OSTEOMYELITIS 2

OSTEOPOROSIS 11

OSTEOPOROSIS FRACT 2

OTITIS EXT 1

OTITIS MED 7

OVAR DIS 30

**OVERDOSE 768**

OVERDOSE ACCID 87

**OVERDOSE INTEND 652**

OVULAT FAIL 1

PAIN 345

PAIN ABDO 394

PAIN BACK 98

PAIN BIL 2

PAIN BONE 33

PAIN BREAST 70

PAIN CHEST 247

PAIN CHEST SUBSTERN 7

PAIN EAR 20

PAIN EYE 61

PAIN INJECT SITE 1

PAIN KIDNEY 3

PAIN NECK 47

PAIN PELVIC 19

PAIN URETHRA 10

PALLOR 13

PALPITAT 212

PANCREAS DIS 3

PANCREATITIS 59

PANCYTOPENIA 22

PAP SMEAR SUSP 3

PAPILLEDEMA 8

NEPHRITIS 7

NEPHROSCLEROSIS 1

NEPHROSIS 8

NERVOUSNESS 1193

NEURALGIA 19

NEURITIS 5

NEURITIS OPTIC 26

NEURITIS PERIPH 31

NEURITIS RETROBULBAR 1

**NEUROLEPTIC MALSYND 54**

NEUROPATHY 59

**NEUROSIS 158**

NO DRUG EFFECT 743

NOCTURIA 10

NODULE SKIN 8

NODULE SUBCUTAN 15

NPN INC 4

NYSTAGMUS 24

OBESITY 3

**OBSTRUCT INTEST 15**

OCCLUS 4

**OCCLUS CAROTID 2****OCCLUS CORONARY 8**

OCCLUS MESENTER 2

OCCLUS MESENTER ART 1

OCCLUS RETINAL ART 1

OCULOGYRIC CRISIS 24

OLIGURIA 16

OPISTHOTONOS 6

ORCHITIS 2

PHARYNGITIS 131

PHLEB 11

PHOSPHATASE ALK INC 84

PHOTOPHOBIA 31

PHOTOSENSITIVITY 126

PIT ACTIV DEC 4

PIT ACTIV INC 7

PLACENTA DIS 7

PLAT ABNORM 14

PLAT ADHESIVE DEC 1

PLEURAL DIS 5

PNEUMONIA 150

PNEUMONIA ASPIR 15

PNEUMONIA EOSINOPHIL 7

PNEUMONIA INTERSTIT 18

**PNEUMOTHORAX 3**

POLYARTERITIS NODOSA 2

POLYCYTHEMIA 6

POLYNEURITIS 3

POLYURIA 21

PORPHYRIA 9

PR PROLONGED 3

PREGN DIS 12

PREGN MULT 3

PREGN TEST FALSE POS 3

**PREGN TOXEMIA 2**

PREGN UNINTEND 1021

PRIAPISM 45

PROCTITIS 1

PROCTITIS ULCER 1

PROLACTIN INC 129

PROSTAT DIS 23

**PARALYSIS 23**  
**PARALYSIS EXTRAOCUL 5**  
**PARALYSIS FACIAL 26**  
**PARALYSIS FLACCID 2**  
**PARALYSIS SPASTIC 3**  
**PARALYSIS VOCAL CORD 4**  
**PARANOID REACT 192**  
**PARAPLEGIA 1**  
PARATHYR DIS 2  
PARESTH CIRCUMORAL 27  
PARESTHESIA 430  
PAROSMIA 20  
PAROTID ENLARGE 7  
PENIS DIS 25  
PEPTIC ULCER SYND 3  
PERICARDITIS 4  
PERINATAL DIS 8  
PERIOST DIS 1  
**PERITONITIS 5**  
PERSON DIS 574  
PETECHIA 33  
RASH VESIC BULL 86  
RBC ABNORM 15  
RE BLOCK 1  
RE HYPERPLASIA 1  
**REACT AGGRAV 868**  
REACT UNEVAL 120  
RECTAL DIS 14  
REFLEXES DEC 7  
REFLEXES INC 24  
REFRACT DIS 9  
RESPIRAT DIS 72  
**RESPIRAT DISTRES SYN 2**  
RETINAL DEGENERAT 9  
RETINAL DETACH 2  
RETINAL DIS 10  
RETINAL PIGMENT 1  
RETINAL VASC DIS 4  
**RHABDO 1**  
RHINITIS 75  
SALICYLISM 1  
SALIV GLAND ENLARGE 12  
SALIVA INC 27  
SALPINGITIS 5  
SARCOIDOSIS 3  
**SCHIZOPHRENIC REACT 20**  
SCLERITIS 3  
SCLERODERMA 3  
**SCLEROSIS MULT 18**  
**SCREAMING SYND 7**  
SEBORRHEA 7  
SEPSIS 23  
SERUM IRON INC 4  
SERUM SICK 80  
SEX FUNC ABNORM 25  
SEX MAT ACCEL 2  
SGOT INC 168  
SGPT INC 155  
**SHOCK 30**  
SINUSITIS 28  
SKIN DIS 25  
SKIN DISCOLOR 69

PROTHROMBIN DEC 77  
PROTHROMBIN INC 14  
PRURITUS 686  
PSA INC 1  
PSORIASIS 24  
**PSYCHOSIS 269**  
PTOSIS 11  
PUPIL DIS 5  
PURPURA 50  
PURPURA THROMBOPEN 35  
PURPURA THROMBOPEN T 3  
PURPURA VASC 4  
PYELONEPHRITIS 5  
PYURIA 3  
QT PROLONGED 40  
RASH 1753  
RASH LE 6  
RASH MAC PAP 185  
RASH PETECH 21  
RASH PURPUR 19  
RASH PUST 16  
SPUTUM INC 3  
ST DEPRESSED 5  
ST ELEVATED 2  
STENO AORTIC 1  
STENO BLADDER 3  
STENO PYLOR 3  
STEVENS JOHNSONSYND 13  
**STILLBIRTH 11**  
STOMACH ATONY 1  
STOMACH DILAT 1  
STOMATITIS 52  
STOMATITIS APHTH 6  
STOMATITIS ULCER 6  
STOOL ABNORM 9  
STRABISMUS 2  
STRIDOR 6  
**STUPOR 137**  
**\*\*SUDDEN DEATH 38\*\***  
**SUICIDE ATTEMPT 2246**  
SWEAT 429  
SWEAT DEC 1  
SYNCOPE 335  
SYNOVITIS 2  
SYPH TEST FALSE POS 1  
T INVERTED 8  
TACHYCARDIA 333  
TACHYCARDIA SUPVENT 29  
TACHYCARDIA VENT 65  
TASTE LOSS 23  
TASTE PERVERS 71  
TENDON DIS 12  
TENDON RUPT 2  
TENESMUS 3  
TENOSYNOVITIS 70  
TESTIS DIS 17  
TETANY 6  
**THINKING ABNORM 652**  
THIRST 25  
**THROM 12**  
**THROM CAROTID 1**  
**THROM CEREBR 3**

SKIN DRY 29  
SKIN STRIAE 2  
**SLEEP DIS 83**  
**SOMNOLENCE 1029**  
SPASM GENERAL 9  
SPEECH DIS 189  
SPERM ARREST 1  
SPLEEN DIS 1  
**SPLEEN RUPT 3**  
SPLENOMEGALY 7  
THYROIDITIS 8  
TINNITUS 220  
TOLER DEC 3  
TOLER INC 166  
TONGUE DIS 15  
TOOTH CARIES 1  
TOOTH DIS 92  
TORSADES DE POINTES 8  
**TORTICOLLIS 21**  
TRANSPOS GREAT VESS 1  
TREMOR 798  
TRISMUS 76  
TWITCH 323  
UG DIS 3  
ULCER CORNEAL 1  
ULCER DUODEN 6  
ULCER DUODEN HEM 7  
ULCER DUODEN PER 2  
ULCER ESOPH 5  
ULCER INTEST 1  
ULCER MOUTH 46  
ULCER PEPTIC 8  
ULCER PEPTIC HEM 5  
ULCER PEPTIC REACT 2  
ULCER SKIN 20  
ULCER STOMACH 12  
ULCER STOMACH HEM 8  
**ULCER STOMACH PER 1**  
UNEXPECTED BENEFIT 244  
UREMIA 2  
URETHRITIS 8  
URICACIDUR 1  
URIN ABNORM 26  
URIN FREQUENCY 110  
URIN IMPAIRED 23

**THROM CEREBR VEN 1**  
**THROM CORONARY 2**  
**THROM PULM 1**  
THROM RETINAL VEIN 3  
THROMBOCYTHEM 26  
THROMBOCYTOPENIA 145  
THROMBOPHLEB 22  
**THROMBOPHLEB DEEP 12**  
THROMBOPLASTIN DEC 13  
THYR DIS 28  
URIN RETENT 162  
URIN TRACT DIS 14  
URIN URGENCY 23  
URTICARIA 595  
UTER ATONY 1  
UTER DIS 7  
UTER ENLARGE 2  
UTER FIBROID DEGEN 1  
UTER FIBROID ENLARGE 8  
UTER RUPT 2  
UTER SPASM 2  
VAGINITIS 38  
VASC DIS 5  
VASC DIS PERIPH 25  
VASCULITIS 62  
VASCULITIS KIDNEY 2  
**VASODILAT 230**  
VEIN VARICOSE 6  
VERTIGO 76  
VESTIBUL DIS 9  
VISION ABNORM 201  
VISUAL FIELD DEFECT 3  
VITREOUS DIS 9  
VOICE ALTERAT 26  
VOMIT 180  
VULVOVAGINAL DIS 5  
VULVOVAGINITIS 2  
WATER INTOX 2  
WBC ABNORM 9  
WEIGHT DEC 507  
WEIGHT INC 533  
**WITHDRAW SYND 329**  
YAWN 71

---

TOTAL INCIDENCES: 64992

TOTAL TERMS: 902 (from 35,230 cases)

\* WARNING!! The incidence counts do NOT represent ADR (Adverse Reaction Reports) counts. Each ADR filed with the FDA may have from 1 to 5 reaction terms recorded per report/case.

Food & Drug Administration, Freedom of Information Staff (HFI-35),

Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857 Telephone (301) 443-6310 “

SSRI site summary:

Total highlighted adverse reactions recorded on this document:

<b>159</b>	<b>(**red - recorded deaths)</b>
<b>1,431</b>	<b>(red - life threatening medical)</b>
<b>17,166</b>	<b>(blue - psychological/cns, including 2246 suicide attempts)</b>
<b>845</b>	<b>(pink - movement disorders/paralysis)</b>