

ADDITIONAL CONDITIONS THAT MAY BE A FOCUS OF CLINICAL ATTENTION

- V15.81 Noncompliance With Treatment
- V65.2 Malingering
- V71.01 Adult Antisocial Behavior
- V71.02 Child or Adolescent Antisocial Behavior
- V62.89 Borderline Intellectual Functioning

Note: This is coded on Axis II.

- 780.9 Age-Related Cognitive Decline
- V62.82 Bereavement
- V62.3 Academic Problem
- V62.2 Occupational Problem
- 313.82 Identity Problem
- V62.89 Religious or Spiritual Problem
- V62.4 Acculturation Problem
- V62.89 Phase of Life Problem

ADDITIONAL CODES

- 300.9 Unspecified Mental Disorder (nonpsychotic)
- V71.09 No Diagnosis or Condition on Axis I
- 799.9 Diagnosis or Condition Deferred on Axis I
- V71.09 No Diagnosis on Axis II
- 799.9 Diagnosis Deferred on Axis II

MULTIAXIAL SYSTEM

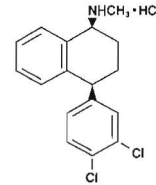
- Axis I Clinical Disorders
Other Conditions That May Be a Focus of Clinical Attention
- Axis II Personality Disorders
Mental Retardation
- Axis III General Medical Conditions
- Axis IV Psychosocial and Environmental Problems
- Axis V Global Assessment of Functioning

Zoloft®

(sertraline hydrochloride)
Tablets

DESCRIPTION

ZOLOFT® (sertraline hydrochloride) is an antidepressant for oral administration. It is chemically unrelated to tricyclic, tetracyclic, or other available antidepressant agents. It has a molecular weight of 342.7. Sertraline hydrochloride has the following chemical name: (1S-cis)-4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-N-methyl-1-naphthalenamine hydrochloride. The empirical formula $C_{17}H_{17}NCl_2 \cdot HCl$ is represented by the following structural formula:



Sertraline hydrochloride is a white crystalline powder that is slightly soluble in water and isopropyl alcohol, and sparingly soluble in ethanol.

ZOLOFT is supplied for oral administration as scored tablets containing sertraline hydrochloride equivalent to 50 and 100 mg of sertraline and the following inactive ingredients: dibasic calcium phosphate dihydrate, FD&C Blue #2 aluminum lake (in 50 mg tablet), hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, sodium starch glycolate, synthetic yellow iron oxide (in 100 mg tablet), and titanium dioxide.

CLINICAL PHARMACOLOGY

Pharmacodynamics

The mechanism of action of sertraline is presumed to be linked to its inhibition of CNS neuronal uptake of serotonin (5HT). Studies at clinically relevant doses in man have demonstrated that sertraline blocks the uptake of serotonin into human platelets. *In vitro* studies in animals also suggest that sertraline is a potent and selective inhibitor of neuronal serotonin reuptake and has only very weak effects on norepinephrine and dopamine neuronal reuptake. *In vitro* studies have shown that sertraline has no significant affinity for adrenergic (α_1 , α_2 , β_1 , β_2), cholinergic, GABA, dopaminergic, histaminergic, serotonergic (5HT_{1A}, 5HT_{1B}, 5HT₂), or benzodiazepine receptors; antagonism of such receptors has been hypothesized to be associated with various anticholinergic, sedative, and cardiovascular effects for other psychotropic drugs. The chronic administration of sertraline was found in animals to downregulate brain norepinephrine receptors, as has been observed with other clinically effective antidepressants. Sertraline does not inhibit monoamine oxidase.

Pharmacokinetics

Systemic Bioavailability—In man, following oral once-daily dosing over the range of 50 to 200 mg for 14 days, mean peak plasma concentrations (C_{max}) of sertraline occurred between 4.5 to 8.4 hours postdosing. The average terminal elimination half-life of plasma sertraline is about 26 hours. Based on this pharmacokinetic parameter, steady-state sertraline plasma levels should be achieved after approximately one week of once-daily dosing. Linear dose-proportional pharmacokinetics were demonstrated in a single dose study in which the C_{max} and area under the plasma concentration time curve (AUC) of sertraline were proportional to dose over a range of 50 to 200 mg. Consistent with the terminal elimination half-life, there is an approximately two-fold accumulation, compared to a single dose, of sertraline with repeated dosing over a 50 to 200 mg dose range. The single dose bioavailability of sertraline tablets is approximately equal to an equivalent dose of solution.

The effects of food on the bioavailability of sertraline were studied in subjects administered a single dose with and without food. AUC was slightly increased when drug was administered with food but the C_{max} was 25% greater, while the time to reach peak plasma concentration decreased from 8 hours post-dosing to 5.5 hours.

Metabolism—Sertraline undergoes extensive first pass metabolism. The principal initial pathway of metabolism for sertraline is N-demethylation. N-desmethylsertraline has a plasma terminal elimination half-life of 62 to 104 hours. Both *in vitro* biochemical and *in vivo* pharmacological testing have shown N-desmethylsertraline to be substantially less active than sertraline. Both sertraline and N-desmethylsertraline undergo oxidative deamination and subsequent reduction, hydroxylation, and glucuronide conjugation. In a study of radiolabeled sertraline involving two healthy male subjects, sertraline accounted for less than 5% of the plasma radioactivity. About 40-45% of the administered radioactivity was recovered in urine in 9 days. Unchanged sertraline was not detectable in the urine. For the same period, about 40-45% of the administered radioactivity was accounted for in feces, including 12-14% unchanged sertraline.

Desmethylsertraline exhibits time-related, dose dependent increases in AUC (0-24 hour), C_{max} and C_{min}, with about a 5-9 fold increase in these pharmacokinetic parameters between day 1 and day 14.

Protein Binding—*In vitro* protein binding studies performed with radiolabeled ³H-sertraline showed that sertraline is highly bound to serum proteins (98%) in the range of 20 to 500 ng/mL. However, at up to 300 and 200 ng/mL concentrations, respectively, sertraline and N-desmethylsertraline did not alter the plasma protein binding of two other highly protein bound drugs, viz., warfarin and propranolol (see Precautions).

Age—Sertraline plasma clearance in a group of 16 (8 male, 8 female) elderly patients treated for 14 days at a dose of 100 mg/day was approximately 40% lower than in a similarly studied group of younger (25 to 32 y.o.) individuals. Steady-state, therefore, should be achieved after 2 to 3 weeks in older patients. The same study showed a decreased clearance of desmethylsertraline in older males, but not in older females.

Liver Disease—As might be predicted from its primary site of metabolism, liver impairment can affect the elimination of sertraline. The elimination half-life of sertraline was prolonged in a single dose study of patients with mild, stable cirrhosis, with a mean of 52 hours compared to 22 hours seen in subjects without liver disease. This suggests that the use of sertraline in patients with liver disease must be approached with caution. If sertraline is administered to patients with liver disease, a lower or less frequent dose should be used (see Precautions and Dosage and Administration).

Renal Disease—The pharmacokinetics of sertraline in patients with significant renal dysfunction have not been determined.

INDICATIONS AND USAGE

ZOLOFT (sertraline hydrochloride) is indicated for the treatment of depression. The efficacy of ZOLOFT in the treatment of a major depressive episode was established in six to eight week controlled trials of out-patients whose diagnoses corresponded most closely to the DSM-III category of major depressive disorder.

A major depressive episode implies a prominent and relatively persistent depressed or dysphoric mood that usually interferes with daily functioning (nearly every day for at least 2 weeks); it should include at least 4 of the following 8 symptoms: change in appetite, change in sleep, psychomotor agitation or retardation, loss of interest in

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FOR FIRST-LINE THERAPY IN DEPRESSION

DSM-IV

CLASSIFICATION

Axis I and II Categories and Codes

An ellipsis (...) is used in the names of certain disorders to indicate that the name of a specific mental disorder or general medical condition should be inserted when recording the name (eg, 293.0 Delirium Due to Hypothyroidism).

An "x" appearing in a diagnostic code indicates that a specific code number is required.

If criteria are currently met, one of the following severity specifiers may be noted after the diagnosis:

- Mild
- Moderate
- Severe

If criteria are no longer met, one of the following specifiers may be noted:

- In Partial Remission
- In Full Remission
- Prior History

NOS = Not Otherwise Specified.

DISORDERS USUALLY FIRST DIAGNOSED IN INFANCY, CHILDHOOD, OR ADOLESCENCE

Mental Retardation

Note: These are coded on Axis II.

- 317 Mild Mental Retardation
- 318.0 Moderate Mental Retardation
- 318.1 Severe Mental Retardation
- 318.2 Profound Mental Retardation
- 319 Mental Retardation, Severity Unspecified

Learning Disorders

- 315.00 Reading Disorder
- 315.1 Mathematics Disorder
- 315.2 Disorder of Written Expression
- 315.9 Learning Disorder NOS

Motor Skills Disorder

- 315.4 Developmental Coordination Disorder

Communication Disorders

- 315.31 Expressive Language Disorder
- 315.31 Mixed Receptive-Expressive Language Disorder
- 315.39 Phonological Disorder
- 307.0 Stuttering
- 307.9 Communication Disorder NOS

Pervasive Developmental Disorders

- 299.00 Autistic Disorder
- 299.80 Rett's Disorder
- 299.10 Childhood Disintegrative Disorder
- 299.80 Asperger's Disorder
- 299.80 Pervasive Developmental Disorder NOS

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FOR FIRST-LINE THERAPY IN DEPRESSION

Attention-Deficit and Disruptive Behavior Disorders

- 314.xx Attention-Deficit/Hyperactivity Disorder
 - .01 Combined Type
 - .00 Predominantly Inattentive Type
 - .01 Predominantly Hyperactive-Impulsive Type
- 314.9 Attention-Deficit/Hyperactivity Disorder NOS
- 312.8 Conduct Disorder
Specify type: Childhood-Onset Type/
Adolescent-Onset Type
- 313.81 Oppositional Defiant Disorder**
- 312.9 Disruptive Behavior Disorder NOS

Feeding and Eating Disorders of Infancy or Early Childhood

- 307.52 Pica
- 307.53 Rumination Disorder
- 307.59 Feeding Disorder of Infancy or Early Childhood

Tic Disorders

- 307.23 Tourette's Disorder**
- 307.22 Chronic Motor or Vocal Tic Disorder
- 307.21 Transient Tic Disorder
Specify if: Single Episode/Recurrent
- 307.20 Tic Disorder NOS

Elimination Disorders

- ___ Encopresis
 - 787.6 With Constipation and Overflow Incontinence
 - 307.7 Without Constipation and Overflow Incontinence
- 307.6 Enuresis (Not Due to a General Medical Condition)
Specify type: Nocturnal Only/Diurnal Only/Nocturnal and Diurnal

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Other Disorders of Infancy, Childhood, or Adolescence

- 309.21 Separation Anxiety Disorder
Specify if: Early Onset
- 313.23 Selective Mutism
- 313.89 Reactive Attachment Disorder of Infancy or Early Childhood
Specify type: Inhibited Type/Disinhibited Type
- 307.3 Stereotypic Movement Disorder
Specify if: With Self-Injurious Behavior
- 313.9 Disorder of Infancy, Childhood, or Adolescence NOS

DELIRIUM, DEMENTIA, AND AMNESTIC AND OTHER COGNITIVE DISORDERS

Delirium

- 293.0 Delirium Due to ... [*Indicate the General Medical Condition*]
- ___ Substance Intoxication Delirium (*refer to Substance-Related Disorders for substance-specific codes*)
- ___ Substance Withdrawal Delirium (*refer to Substance-Related Disorders for substance-specific codes*)
- ___ Delirium Due to Multiple Etiologies (*code each of the specific etiologies*)
- 780.09 Delirium NOS

Dementia

- 290.xx Dementia of the Alzheimer's Type, With Early Onset (*also code 331.0 Alzheimer's disease on Axis III*)
 - .10 Uncomplicated
 - .11 With Delirium
 - .12 With Delusions
 - .13 With Depressed Mood*Specify if:* With Behavioral Disturbance

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- 290.xx Dementia of the Alzheimer's Type, With Late Onset (*also code 331.0 Alzheimer's disease on Axis III*)
 - .0 Uncomplicated
 - .3 With Delirium
 - .20 With Delusions
 - .21 With Depressed Mood

Specify if: With Behavioral Disturbance
- 290.xx Vascular Dementia
 - .40 Uncomplicated
 - .41 With Delirium
 - .42 With Delusions
 - .43 With Depressed Mood

Specify if: With Behavioral Disturbance
- 294.9 Dementia Due to HIV Disease (*also code 043.1 HIV infection affecting central nervous system on Axis III*)
- 294.1 Dementia Due to Head Trauma (*also code 854.00 head injury on Axis III*)
- 294.1 Dementia Due to Parkinson's Disease (*also code 332.0 Parkinson's disease on Axis III*)
- 294.1 Dementia Due to Huntington's Disease (*also code 333.4 Huntington's disease on Axis III*)
- 290.10 Dementia Due to Pick's Disease (*also code 331.1 Pick's disease on Axis III*)
- 290.10 Dementia Due to Creutzfeldt-Jakob Disease (*also code 046.1 Creutzfeldt-Jakob disease on Axis III*)
- 294.1 Dementia Due to ... [*Indicate the General Medical Condition not listed above*] (*also code the general medical condition on Axis III*)

- _____ Substance-Induced Persisting Dementia (*refer to Substance-Related Disorders for substance-specific codes*)
- _____ Dementia Due to Multiple Etiologies (*code each of the specific etiologies*)
- 294.8 Dementia NOS

Amnestic Disorders

- 294.0 Amnestic Disorder Due to ... [*Indicate the General Medical Condition*]

Specify if: Transient/Chronic
- _____ Substance-Induced Persisting Amnestic Disorder (*refer to Substance-Related Disorders for substance-specific codes*)
- 294.8 Amnestic Disorder NOS

Other Cognitive Disorders

- 294.9 Cognitive Disorder NOS

MENTAL DISORDERS DUE TO A GENERAL MEDICAL CONDITION NOT ELSEWHERE CLASSIFIED

- 293.89 Catatonic Disorder Due to ... [*Indicate the General Medical Condition*]
- 310.1 Personality Change Due to ... [*Indicate the General Medical Condition*]

Specify type: Labile Type/Disinhibited Type/Aggressive Type/Apathetic Type/Paranoid Type/Other Type/Combined Type/Unspecified Type
- 293.9 Mental Disorder NOS Due to ... [*Indicate the General Medical Condition*]

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FOR FIRST-LINE THERAPY IN DEPRESSION

SUBSTANCE-RELATED DISORDERS

^aThe following specifiers may be applied to Substance Dependence:

- With Physiological Dependence/Without Physiological Dependence
- Early Full Remission/Early Partial Remission
- Sustained Full Remission/Sustained Partial Remission
- On Agonist Therapy/In a Controlled Environment

The following specifiers apply to Substance-Induced Disorders as noted:

- ^lWith Onset During Intoxication/^wWith Onset During Withdrawal

ALCOHOL-RELATED DISORDERS

Alcohol Use Disorders

- 303.90 Alcohol Dependence^a
- 305.00 Alcohol Abuse

Alcohol-Induced Disorders

- 303.00 Alcohol Intoxication
- 291.8 Alcohol Withdrawal
 - Specify if:* With Perceptual Disturbances
- 291.0 Alcohol Intoxication Delirium
- 291.0 Alcohol Withdrawal Delirium
- 291.2 Alcohol-Induced Persisting Dementia
- 291.1 Alcohol-Induced Persisting Amnestic Disorder
- 291.x Alcohol-Induced Psychotic Disorder
 - .5 With Delusions^{l,w}
 - .3 With Hallucinations^{l,w}
- 291.8 Alcohol-Induced Mood Disorder^{l,w}
- 291.8 Alcohol-Induced Anxiety Disorder^{l,w}
- 291.8 Alcohol-Induced Sexual Dysfunction^l
- 291.8 Alcohol-Induced Sleep Disorder^{l,w}
- 291.9 Alcohol-Related Disorder NOS

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AMPHETAMINE (OR AMPHETAMINE-LIKE)-RELATED DISORDERS

Amphetamine Use Disorders

- 304.40 Amphetamine Dependence^a
- 305.70 Amphetamine Abuse

Amphetamine-Induced Disorders

- 292.89 Amphetamine Intoxication
 - Specify if:* With Perceptual Disturbances
- 292.0 Amphetamine Withdrawal
- 292.81 Amphetamine Intoxication Delirium
- 292.xx Amphetamine-Induced Psychotic Disorder
 - .11 With Delusions^l
 - .12 With Hallucinations^l
- 292.84 Amphetamine-Induced Mood Disorder^{l,w}
- 292.89 Amphetamine-Induced Anxiety Disorder^l
- 292.89 Amphetamine-Induced Sexual Dysfunction^l
- 292.89 Amphetamine-Induced Sleep Disorder^{l,w}
- 292.9 Amphetamine-Related Disorder NOS

CAFFEINE-RELATED DISORDERS

Caffeine-Induced Disorders

- 305.90 Caffeine Intoxication
- 292.89 Caffeine-Induced Anxiety Disorder^l
- 292.89 Caffeine-Induced Sleep Disorder^l
- 292.9 Caffeine-Related Disorder NOS

CANNABIS-RELATED DISORDERS

Cannabis Use Disorders

- 304.30 Cannabis Dependence^a
- 305.20 Cannabis Abuse

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FOR FIRST-LINE THERAPY IN DEPRESSION

Cannabis-Induced Disorders

- 292.89 Cannabis Intoxication
Specify if: With Perceptual Disturbances
- 292.81 Cannabis Intoxication Delirium
- 292.xx Cannabis-Induced Psychotic Disorder
 - .11 With Delusions¹
 - .12 With Hallucinations¹
- 292.89 Cannabis-Induced Anxiety Disorder¹
- 292.9 Cannabis-Related Disorder NOS

COCAINE-RELATED DISORDERS

Cocaine Use Disorders

- 304.20 Cocaine Dependence^a
- 305.60 Cocaine Abuse

Cocaine-Induced Disorders

- 292.89 Cocaine Intoxication
Specify if: With Perceptual Disturbances
- 292.0 Cocaine Withdrawal
- 292.81 Cocaine Intoxication Delirium
- 292.xx Cocaine-Induced Psychotic Disorder
 - .11 With Delusions¹
 - .12 With Hallucinations¹
- 292.84 Cocaine-Induced Mood Disorder^{1,w}
- 292.89 Cocaine-Induced Anxiety Disorder^{1,w}
- 292.89 Cocaine-Induced Sexual Dysfunction¹
- 292.89 Cocaine-Induced Sleep Disorder^{1,w}
- 292.9 Cocaine-Related Disorder NOS

HALLUCINOGEN-RELATED DISORDERS

Hallucinogen Use Disorders

- 304.50 Hallucinogen Dependence^a
- 305.30 Hallucinogen Abuse

Hallucinogen-Induced Disorders

- 292.89 Hallucinogen Intoxication
- 292.89 Hallucinogen Persisting Perception Disorder (Flashbacks)

- 292.81 Hallucinogen Intoxication Delirium
- 292.xx Hallucinogen-Induced Psychotic Disorder
 - .11 With Delusions¹
 - .12 With Hallucinations¹
- 292.84 Hallucinogen-Induced Mood Disorder¹
- 292.89 Hallucinogen-Induced Anxiety Disorder¹
- 292.9 Hallucinogen-Related Disorder NOS

INHALANT-RELATED DISORDERS

Inhalant Use Disorders

- 304.60 Inhalant Dependence^a
- 305.90 Inhalant Abuse

Inhalant-Induced Disorders

- 292.89 Inhalant Intoxication
- 292.81 Inhalant Intoxication Delirium
- 292.82 Inhalant-Induced Persisting Dementia
- 292.xx Inhalant-Induced Psychotic Disorder
 - .11 With Delusions¹
 - .12 With Hallucinations¹
- 292.84 Inhalant-Induced Mood Disorder¹
- 292.89 Inhalant-Induced Anxiety Disorder¹
- 292.9 Inhalant-Related Disorder NOS

NICOTINE-RELATED DISORDERS

Nicotine Use Disorder

- 305.10 Nicotine Dependence^a

Nicotine-Induced Disorder

- 292.0 Nicotine Withdrawal
- 292.9 Nicotine-Related Disorder NOS

OPIOID-RELATED DISORDERS

Opioid Use Disorders

- 304.00 Opioid Dependence^a
- 305.50 Opioid Abuse

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FOR FIRST-LINE THERAPY IN DEPRESSION

Opioid-Induced Disorders

- 292.89 Opioid Intoxication
Specify if: With Perceptual Disturbances
- 292.0 Opioid Withdrawal
- 292.81 Opioid Intoxication Delirium
- 292.xx Opioid-Induced Psychotic Disorder
 - .11 With Delusions¹
 - .12 With Hallucinations¹
- 292.84 Opioid-Induced Mood Disorder¹
- 292.89 Opioid-Induced Sexual Dysfunction¹
- 292.89 Opioid-Induced Sleep Disorder^{1,W}
- 292.9 Opioid-Related Disorder NOS

PHENCYCLIDINE (OR PHENCYCLIDINE-LIKE)-RELATED DISORDERS

Phencyclidine Use Disorders

- 304.90 Phencyclidine Dependence^a
- 305.90 Phencyclidine Abuse

Phencyclidine-Induced Disorders

- 292.89 Phencyclidine Intoxication
Specify if: With Perceptual Disturbances
- 292.81 Phencyclidine Intoxication Delirium
- 292.xx Phencyclidine-Induced Psychotic Disorder
 - .11 With Delusions¹
 - .12 With Hallucinations¹
- 292.84 Phencyclidine-Induced Mood Disorder¹
- 292.89 Phencyclidine-Induced Anxiety Disorder¹
- 292.9 Phencyclidine-Related Disorder NOS

SEDATIVE-, HYPNOTIC-, OR ANXIOLYTIC-RELATED DISORDERS

Sedative, Hypnotic, or Anxiolytic Use Disorders

- 304.10 Sedative, Hypnotic, or Anxiolytic Dependence^a
- 305.40 Sedative, Hypnotic, or Anxiolytic Abuse

Sedative-, Hypnotic-, or Anxiolytic-Induced Disorders

- 292.89 Sedative, Hypnotic, or Anxiolytic Intoxication
- 292.0 Sedative, Hypnotic, or Anxiolytic Withdrawal
Specify if: With Perceptual Disturbances
- 292.81 Sedative, Hypnotic, or Anxiolytic Intoxication Delirium
- 292.81 Sedative, Hypnotic, or Anxiolytic Withdrawal Delirium
- 292.82 Sedative-, Hypnotic-, or Anxiolytic-Induced Persisting Dementia
- 292.83 Sedative-, Hypnotic-, or Anxiolytic-Induced Persisting Amnestic Disorder
- 292.xx Sedative-, Hypnotic-, or Anxiolytic-Induced Psychotic Disorder
 - .11 With Delusions^{1,W}
 - .12 With Hallucinations^{1,W}
- 292.84 Sedative-, Hypnotic-, or Anxiolytic-Induced Mood Disorder^{1,W}
- 292.89 Sedative-, Hypnotic-, or Anxiolytic-Induced Anxiety Disorder^W
- 292.89 Sedative-, Hypnotic-, or Anxiolytic-Induced Sexual Dysfunction¹
- 292.89 Sedative-, Hypnotic-, or Anxiolytic-Induced Sleep Disorder^{1,W}
- 292.9 Sedative-, Hypnotic-, or Anxiolytic-Related Disorder NOS

POLYSUBSTANCE-RELATED DISORDER

- 304.80 Polysubstance Dependence^a

OTHER (OR UNKNOWN) SUBSTANCE-RELATED DISORDERS

Other (or Unknown) Substance Use Disorders

- 304.90 Other (or Unknown) Substance Dependence^a
- 305.90 Other (or Unknown) Substance Abuse

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FOR FIRST-LINE THERAPY IN DEPRESSION

Other (or Unknown) Substance-Induced Disorders

- 292.89 Other (or Unknown) Substance Intoxication
Specify if: With Perceptual Disturbances
- 292.0 Other (or Unknown) Substance Withdrawal
Specify if: With Perceptual Disturbances
- 292.81 Other (or Unknown) Substance-Induced Delirium
- 292.82 Other (or Unknown) Substance-Induced Persisting Dementia
- 292.83 Other (or Unknown) Substance-Induced Persisting Amnestic Disorder
- 292.xx Other (or Unknown) Substance-Induced Psychotic Disorder
 - .11 With Delusions^{1,W}
 - .12 With Hallucinations^{1,W}
- 292.84 Other (or Unknown) Substance-Induced Mood Disorder^{1,W}
- 292.89 Other (or Unknown) Substance-Induced Anxiety Disorder^{1,W}
- 292.89 Other (or Unknown) Substance-Induced Sexual Dysfunction¹
- 292.89 Other (or Unknown) Substance-Induced Sleep Disorder^{1,W}
- 292.9 Other (or Unknown) Substance-Related Disorder NOS

SCHIZOPHRENIA AND OTHER PSYCHOTIC DISORDERS

295.xx Schizophrenia

The following Classification of Longitudinal Course applies to all subtypes of Schizophrenia:

- Episodic With Interepisode Residual Symptoms
(specify if: With Prominent Negative Symptoms)/Episodic With No Interepisode Residual Symptoms

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Continuous

(specify if: With Prominent Negative Symptoms)

Single Episode In Partial Remission

(specify if: With Prominent Negative Symptoms)/Single Episode In Full Remission

Other or Unspecified Pattern

.30 Paranoid Type

.10 Disorganized Type

.20 Catatonic Type

.90 Undifferentiated Type

.60 Residual Type

295.40 Schizophreniform Disorder

Specify if: Without Good Prognostic Features/With Good Prognostic Features

295.70 Schizoaffective Disorder

Specify type: Bipolar Type/Depressive Type

297.1 Delusional Disorder

Specify type: Erotomanic Type/Grandiose Type/Jealous Type/Persecutory Type/Somatic Type/Mixed Type/Unspecified Type

298.8 Brief Psychotic Disorder

Specify if: With Marked Stressor(s)/Without Marked Stressor(s)/With Postpartum Onset

297.3 Shared Psychotic Disorder

293.xx Psychotic Disorder Due to ... *[Indicate the General Medical Condition]*

.81 With Delusions

.82 With Hallucinations

Substance-Induced Psychotic Disorder
(refer to Substance-Related Disorders for substance-specific codes)

Specify if: With Onset During Intoxication/With Onset During Withdrawal

298.9 Psychotic Disorder NOS

FOR FIRST-LINE THERAPY IN DEPRESSION

MOOD DISORDERS

Code current state of Major Depressive Disorder or Bipolar I Disorder in fifth digit:

- 1 = Mild
- 2 = Moderate
- 3 = Severe Without Psychotic Features
- 4 = Severe With Psychotic Features
 - Specify: Mood-Congruent Psychotic Features/Mood-Incongruent Psychotic Features
- 5 = In Partial Remission
- 6 = In Full Remission
- 0 = Unspecified

The following specifiers apply (for current or most recent episode) to Mood Disorders as noted:

- ^aSeverity/Psychotic/Remission Specifiers/^bChronic/^cWith Catatonic Features/^dWith Melancholic Features/^eWith Atypical Features/^fWith Postpartum Onset

The following specifiers apply to Mood Disorders as noted:

- ^gWith or Without Full Interepisode Recovery/^hWith Seasonal Pattern/ⁱWith Rapid Cycling

DEPRESSIVE DISORDERS

- 296.xx **Major Depressive Disorder,**
 - .2x Single Episode^{a,b,c,d,e,f}
 - .3x Recurrent^{a,b,c,d,e,f,g,h}
- 300.4 **Dysthymic Disorder**
 - Specify if: Early Onset/Late Onset
 - Specify: With Atypical Features
- 311 Depressive Disorder NOS

BIPOLAR DISORDERS

- 296.xx **Bipolar I Disorder,**
 - .0x Single Manic Episode^{a,c,f}
 - Specify if: Mixed
 - .40 Most Recent Episode Hypomanic^{g,h,i}
 - .4x Most Recent Episode Manic^{a,c,f,g,h,i}
 - .6x Most Recent Episode Mixed^{a,c,f,g,h,i}
 - .5x Most Recent Episode Depressed^{a,b,c,d,e,f,g,h,i}
 - .7 Most Recent Episode Unspecified^{g,h,i}
- 296.89 Bipolar II Disorder^{a,b,c,d,e,f,g,h,i}
 - Specify (current or most recent episode): Hypomanic/Depressed
- 301.13 Cyclothymic Disorder
- 296.80 Bipolar Disorder NOS
- 293.83 Mood Disorder Due to ...[Indicate the General Medical Condition]
 - Specify type: With Depressive Features/With Major Depressive-Like Episode/With Manic Features/With Mixed Features
- _____ Substance-Induced Mood Disorder (refer to Substance-Related Disorders for substance-specific codes)
 - Specify type: With Depressive Features/With Manic Features/With Mixed Features
 - Specify if: With Onset During Intoxication/With Onset During Withdrawal
- 296.90 Mood Disorder NOS

ANXIETY DISORDERS

- 300.01 **Panic Disorder Without Agoraphobia**
- 300.21 **Panic Disorder With Agoraphobia**
- 300.22 Agoraphobia Without History of Panic Disorder
- 300.29 **Specific Phobia**
 - Specify type: Animal Type/Natural Environment Type/Blood-Injection-Injury Type/Situational Type/Other Type

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- 300.23 Social Phobia
Specify if: Generalized
- 300.3 Obsessive-Compulsive Disorder
Specify if: With Poor Insight
- 309.81 Posttraumatic Stress Disorder
Specify if: Acute/Chronic
Specify if: With Delayed Onset
- 308.3 Acute Stress Disorder
- 300.02 **Generalized Anxiety Disorder**
- 293.89 Anxiety Disorder Due to ... [*Indicate the General Medical Condition*]
Specify if: With Generalized Anxiety/With Panic Attacks/With Obsessive-Compulsive Symptoms
- _____ Substance-Induced Anxiety Disorder (*refer to Substance-Related Disorders for substance-specific codes*)
Specify if: With Generalized Anxiety/With Panic Attacks/With Obsessive-Compulsive Symptoms/With Phobic Symptoms
Specify if: With Onset During Intoxication/With Onset During Withdrawal
- 300.00 Anxiety Disorder NOS

SOMATOFORM DISORDERS

- 300.81 Somatization Disorder
- 300.81 Undifferentiated Somatoform Disorder
- 300.11 Conversion Disorder
Specify type: With Motor Symptom or Deficit/With Sensory Symptom or Deficit/With Seizures or Convulsions/With Mixed Presentation
- 307.xx Pain Disorder
 - .80 Associated With Psychological Factors
 - .89 Associated With Both Psychological Factors and a General Medical Condition*Specify if:* Acute/Chronic

- 300.7 Hypochondriasis
Specify if: With Poor Insight
- 300.7 Body Dysmorphic Disorder
- 300.81 Somatoform Disorder NOS

FACTITIOUS DISORDERS

- 300.xx **Factitious Disorder**
 - .16 With Predominantly Psychological Signs and Symptoms
 - .19 With Predominantly Physical Signs and Symptoms
 - .19 With Combined Psychological and Physical Signs and Symptoms
- 300.19 Factitious Disorder NOS

DISSOCIATIVE DISORDERS

- 300.12 **Dissociative Amnesia**
- 300.13 **Dissociative Fugue**
- 300.14 Dissociative Identity Disorder**
- 300.6 Depersonalization Disorder
- 300.15 Dissociative Disorder NOS

SEXUAL AND GENDER IDENTITY DISORDERS

SEXUAL DYSFUNCTIONS

The following specifiers apply to all primary Sexual Dysfunctions:

- Lifelong Type/Acquired Type
- Generalized Type/Situational Type
- Due to Psychological Factors/Due to Combined Factors

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Sexual Desire Disorders

- 302.71 Hypoactive Sexual Desire Disorder
- 302.79 Sexual Aversion Disorder

Sexual Arousal Disorders

- 302.72 Female Sexual Arousal Disorder
- 302.72 Male Erectile Disorder

Orgasmic Disorders

- 302.73 Female Orgasmic Disorder
- 302.74 Male Orgasmic Disorder
- 302.75 Premature Ejaculation

Sexual Pain Disorders

- 302.76 Dyspareunia (Not Due to a General Medical Condition)
- 306.51 Vaginismus (Not Due to a General Medical Condition)

Sexual Dysfunction Due to a General Medical Condition

- 625.8 Female Hypoactive Sexual Desire Disorder Due to ... [Indicate the General Medical Condition]
- 608.89 Male Hypoactive Sexual Desire Disorder Due to ... [Indicate the General Medical Condition]
- 607.84 Male Erectile Disorder Due to ... [Indicate the General Medical Condition]
- 625.0 Female Dyspareunia Due to ... [Indicate the General Medical Condition]
- 608.89 Male Dyspareunia Due to ... [Indicate the General Medical Condition]
- 625.8 Other Female Sexual Dysfunction Due to ... [Indicate the General Medical Condition]
- 608.89 Other Male Sexual Dysfunction Due to ... [Indicate the General Medical Condition]
- _____ Substance-Induced Sexual Dysfunction (refer to Substance-Related Disorders for

substance-specific codes)

Specify if: With Impaired Desire/With Impaired Arousal/With Impaired Orgasm/With Sexual Pain
Specify if: With Onset During Intoxication

- 302.70 Sexual Dysfunction NOS

PARAPHILIAS

- 302.4 Exhibitionism
- 302.81 Fetishism
- 302.89 Frotteurism
- 302.2 Pedophilia
Specify if: Sexually Attracted to Males/Sexually Attracted to Females/Sexually Attracted to Both
Specify if: Limited to Incest
Specify type: Exclusive Type/Nonexclusive Type
- 302.83 Sexual Masochism
- 302.84 Sexual Sadism
- 302.3 Transvestic Fetishism
Specify if: With Gender Dysphoria
- 302.82 Voyeurism
- 302.9 Paraphilia NOS

GENDER IDENTITY DISORDERS

- 302.xx Gender Identity Disorder
 - .6 in Children
 - .85 in Adolescents or Adults*Specify if:* Sexually Attracted to Males/Sexually Attracted to Females/Sexually Attracted to Both/Sexually Attracted to Neither
- 302.6 Gender Identity Disorder NOS
- 302.9 Sexual Disorder NOS

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FOR FIRST-LINE THERAPY IN DEPRESSION

EATING DISORDERS

- 307.1 Anorexia Nervosa
Specify type: Restricting Type; Binge-Eating/Purging Type
- 307.51 Bulimia Nervosa
Specify type: Purging Type/Nonpurging Type
- 307.50 Eating Disorder NOS

SLEEP DISORDERS

PRIMARY SLEEP DISORDERS

Dyssomnias

- 307.42 Primary Insomnia
- 307.44 Primary Hypersomnia
Specify if: Recurrent
- 347 Narcolepsy
- 780.59 Breathing-Related Sleep Disorder
- 307.45 Circadian Rhythm Sleep Disorder
Specify type: Delayed Sleep Phase Type/Jet Lag Type/Shift Work Type/Unspecified Type
- 307.47 Dyssomnia NOS

Parasomnias

- 307.47 Nightmare Disorder
- 307.46 Sleep Terror Disorder
- 307.46 Sleepwalking Disorder
- 307.47 Parasomnia NOS

SLEEP DISORDERS RELATED TO ANOTHER MENTAL DISORDER

- 307.42 Insomnia Related to ... [*Indicate the Axis I or Axis II Disorder*]
- 307.44 Hypersomnia Related to ... [*Indicate the Axis I or Axis II Disorder*]

OTHER SLEEP DISORDERS

- 780.xx Sleep Disorder Due to ... [*Indicate the General Medical Condition*]
- .52 Insomnia Type
- .54 Hypersomnia Type
- .59 Parasomnia Type
- .59 Mixed Type
- _____ Substance-Induced Sleep Disorder (*refer to Substance-Related Disorders for substance-specific codes*)
Specify type: Insomnia Type/Hypersomnia Type/Parasomnia Type/Mixed Type
Specify if: With Onset During Intoxication/With Onset During Withdrawal

IMPULSE-CONTROL DISORDERS NOT ELSEWHERE CLASSIFIED

- 312.34 Intermittent Explosive Disorder
- 312.32 Kleptomania
- 312.33 Pyromania
- 312.31 Pathological Gambling
- 312.39 Trichotillomania
- 312.30 Impulse-Control Disorder NOS

ADJUSTMENT DISORDERS

- 309.xx Adjustment Disorder
- .0 With Depressed Mood
- .24 With Anxiety
- .28 With Mixed Anxiety and Depressed Mood
- .3 With Disturbance of Conduct
- .4 With Mixed Disturbance of Emotions and Conduct
- .9 Unspecified
Specify if: Acute/Chronic

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PERSONALITY DISORDERS

Note: These are coded on Axis II.

- 301.0 Paranoid Personality Disorder
- 301.20 Schizoid Personality Disorder
- 301.22 Schizotypal Personality Disorder
- 301.7 Antisocial Personality Disorder
- 301.83 Borderline Personality Disorder
- 301.50 Histrionic Personality Disorder
- 301.81 Narcissistic Personality Disorder
- 301.82 Avoidant Personality Disorder
- 301.6 Dependent Personality Disorder
- 301.4 Obsessive-Compulsive Personality Disorder
- 301.9 Personality Disorder NOS

OTHER CONDITIONS THAT MAY BE A FOCUS OF CLINICAL ATTENTION

PSYCHOLOGICAL FACTORS AFFECTING MEDICAL CONDITION

- 316 ... [Specified Psychological Factor] Affecting ... [Indicate the General Medical Condition]
Choose name based on nature of factors:
 - Mental Disorder Affecting Medical Condition
 - Psychological Symptoms Affecting Medical Condition
 - Personality Traits or Coping Style Affecting Medical Condition
 - Maladaptive Health Behaviors Affecting Medical Condition
 - Stress-Related Physiological Response Affecting Medical Condition
 - Other or Unspecified Psychological Factors Affecting Medical Condition

MEDICATION-INDUCED MOVEMENT DISORDERS

- 332.1 Neuroleptic-Induced Parkinsonism
- 333.92 Neuroleptic Malignant Syndrome
- 333.7 Neuroleptic-Induced Acute Dystonia
- 333.99 Neuroleptic-Induced Acute Akathisia
- 333.82 Neuroleptic-Induced Tardive Dyskinesia
- 333.1 Medication-Induced Postural Tremor
- 333.90 Medication-Induced Movement Disorder NOS

OTHER MEDICATION-INDUCED DISORDER

- 995.2 Adverse Effects of Medication NOS

RELATIONAL PROBLEMS

- V61.9 Relational Problem Related to a Mental Disorder or General Medical Condition
- V61.20 Parent-Child Relational Problem
- V61.1 Partner Relational Problem
- V61.8 Sibling Relational Problem
- V62.81 Relational Problem NOS

PROBLEMS RELATED TO ABUSE OR NEGLECT

- V61.21 Physical Abuse of Child (*code 995.5 if focus of attention is on victim*)
- V61.21 Sexual Abuse of Child (*code 995.5 if focus of attention is on victim*)
- V61.21 Neglect of Child (*code 995.5 if focus of attention is on victim*)
- V61.1 Physical Abuse of Adult (*code 995.81 if focus of attention is on victim*)
- V61.1 Sexual Abuse of Adult (*code 995.81 if focus of attention is on victim*)

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ADDITIONAL CONDITIONS THAT MAY BE A FOCUS OF CLINICAL ATTENTION

- V15.81 Noncompliance With Treatment
- V65.2 Malingering
- V71.01 Adult Antisocial Behavior
- V71.02 Child or Adolescent Antisocial Behavior
- V62.89 Borderline Intellectual Functioning
- Note:** This is coded on Axis II.
- 780.9 Age-Related Cognitive Decline
- V62.82 Bereavement
- V62.3 Academic Problem
- V62.2 Occupational Problem
- 313.82 Identity Problem
- V62.89 Religious or Spiritual Problem
- V62.4 Acculturation Problem
- V62.89 Phase of Life Problem

ADDITIONAL CODES

- 300.9 Unspecified Mental Disorder (nonpsychotic)
- V71.09 No Diagnosis or Condition on Axis I
- 799.9 Diagnosis or Condition Deferred on Axis I
- V71.09 No Diagnosis on Axis II
- 799.9 Diagnosis Deferred on Axis II

MULTIAXIAL SYSTEM

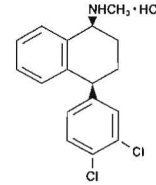
- Axis I Clinical Disorders
Other Conditions That May Be a Focus of Clinical Attention
- Axis II Personality Disorders
Mental Retardation
- Axis III General Medical Conditions
- Axis IV Psychosocial and Environmental Problems
- Axis V Global Assessment of Functioning

Zoloft®

(sertraline hydrochloride)
Tablets

DESCRIPTION

ZOLOFT® (sertraline hydrochloride) is an antidepressant for oral administration. It is chemically unrelated to tricyclic, tetracyclic, or other available antidepressant agents. It has a molecular weight of 342.7. Sertraline hydrochloride has the following chemical name: (1S-cis)-4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-N-methyl-1-naphthalenamine hydrochloride. The empirical formula $C_{17}H_{17}NCl_2 \cdot HCl$ is represented by the following structural formula:



Sertraline hydrochloride is a white crystalline powder that is slightly soluble in water and isopropyl alcohol, and sparingly soluble in ethanol.

ZOLOFT is supplied for oral administration as scored tablets containing sertraline hydrochloride equivalent to 50 and 100 mg of sertraline and the following inactive ingredients: dibasic calcium phosphate dihydrate, FD&C Blue #2 aluminum lake (in 50 mg tablet), hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, sodium starch glycolate, synthetic yellow iron oxide (in 100 mg tablet), and titanium dioxide.

CLINICAL PHARMACOLOGY

Pharmacodynamics

The mechanism of action of sertraline is presumed to be linked to its inhibition of CNS neuronal uptake of serotonin (5HT). Studies at clinically relevant doses in man have demonstrated that sertraline blocks the uptake of serotonin into human platelets. *In vitro* studies in animals also suggest that sertraline is a potent and selective inhibitor of neuronal serotonin reuptake and has only very weak effects on norepinephrine and dopamine neuronal reuptake. *In vitro* studies have shown that sertraline has no significant affinity for adrenergic (alpha, alpha, beta), cholinergic, GABA, dopaminergic, histaminergic, serotonergic (5HT_{1A}, 5HT_{1B}, 5HT_{2A}, 5HT_{2B}), or benzodiazepine receptors; antagonism of such receptors has been hypothesized to be associated with various anticholinergic, sedative, and cardiovascular effects for other psychotropic drugs. The chronic administration of sertraline was found in animals to downregulate brain norepinephrine receptors, as has been observed with other clinically effective antidepressants. Sertraline does not inhibit monoamine oxidase.

Pharmacokinetics

Systemic Bioavailability—In man, following oral once-daily dosing over the range of 50 to 200 mg for 14 days, mean peak plasma concentrations (C_{max}) of sertraline occurred between 4.5 to 8.4 hours postdosing. The average terminal elimination half-life of plasma sertraline is about 26 hours. Based on this pharmacokinetic parameter, steady-state sertraline plasma levels should be achieved after approximately one week of once-daily dosing. Linear dose-proportional pharmacokinetics were demonstrated in a single dose study in which the C_{max} and area under the plasma concentration time curve (AUC) of sertraline were proportional to dose over a range of 50 to 200 mg. Consistent with the terminal elimination half-life, there is an approximately two-fold accumulation, compared to a single dose, of sertraline with repeated dosing over a 50 to 200 mg dose range. The single dose bioavailability of sertraline tablets is approximately equal to an equivalent dose of solution.

The effects of food on the bioavailability of sertraline were studied in subjects administered a single dose with and without food. AUC was slightly increased when drug was administered with food but the C_{max} was 25% greater, while the time to reach peak plasma concentration decreased from 8 hours post-dosing to 5.5 hours.

Metabolism—Sertraline undergoes extensive first pass metabolism. The principal initial pathway of metabolism for sertraline is N-demethylation. N-desmethylsertraline has a plasma terminal elimination half-life of 62 to 104 hours. Both *in vitro* biochemical and *in vivo* pharmacological testing have shown N-desmethylsertraline to be substantially less active than sertraline. Both sertraline and N-desmethylsertraline undergo oxidative deamination and subsequent reduction, hydroxylation, and glucuronide conjugation. In a study of radiolabeled sertraline involving two healthy male subjects, sertraline accounted for less than 5% of the plasma radioactivity. About 40-45% of the administered radioactivity was recovered in urine in 9 days. Unchanged sertraline was not detectable in the urine. For the same period, about 40-45% of the administered radioactivity was accounted for in feces, including 12-14% unchanged sertraline.

Desmethylsertraline exhibits time-related, dose dependent increases in AUC (0-24 hour), C_{max} and C_{min}, with about a 5-9 fold increase in these pharmacokinetic parameters between day 1 and day 14.

Protein Binding—*In vitro* protein binding studies performed with radiolabeled ³H-sertraline showed that sertraline is highly bound to serum proteins (98%) in the range of 20 to 500 ng/mL. However, at up to 300 and 200 ng/mL concentrations, respectively, sertraline and N-desmethylsertraline did not alter the plasma protein binding of two other highly protein bound drugs, viz., warfarin and propranolol (see Precautions).

Age—Sertraline plasma clearance in a group of 16 (8 male, 8 female) elderly patients treated for 14 days at a dose of 100 mg/day was approximately 40% lower than in a similarly studied group of younger (25 to 32 y.o.) individuals. Steady-state, therefore, should be achieved after 2 to 3 weeks in older patients. The same study showed a decreased clearance of desmethylsertraline in older males, but not in older females.

Liver Disease—As might be predicted from its primary site of metabolism, liver impairment can affect the elimination of sertraline. The elimination half-life of sertraline was prolonged in a single dose study of patients with mild, stable cirrhosis, with a mean of 52 hours compared to 22 hours seen in subjects without liver disease. This suggests that the use of sertraline in patients with liver disease must be approached with caution. If sertraline is administered to patients with liver disease, a lower or less frequent dose should be used (see Precautions and Dosage and Administration).

Renal Disease—The pharmacokinetics of sertraline in patients with significant renal dysfunction have not been determined.

INDICATIONS AND USAGE

ZOLOFT (sertraline hydrochloride) is indicated for the treatment of depression. The efficacy of ZOLOFT in the treatment of a major depressive episode was established in six to eight week controlled trials of out-patients whose diagnoses corresponded most closely to the DSM-III category of major depressive disorder.

A major depressive episode implies a prominent and relatively persistent depressed or dysphoric mood that usually interferes with daily functioning (nearly every day for at least 2 weeks); it should include at least 4 of the following 8 symptoms: change in appetite, change in sleep, psychomotor agitation or retardation, loss of interest in

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Global Assessment of Functioning (GAF) Scale

Consider psychological, social, and occupational functioning on a hypothetical continuum of mental health–illness. Do not include impairment in functioning due to physical (or environmental) limitations.

Code (Note: Use intermediate codes when appropriate, e.g., 45, 68, 72.)

- 100 **Superior functioning in a wide range of activities, life's problems never seem to get out of hand, is sought out by others because of his or her many positive qualities. No symptoms.**
- 91
- 90 **Absent or minimal symptoms** (e.g., mild anxiety before an exam), **good functioning in all areas, interested and involved in a wide range of activities, socially effective, generally satisfied with life, no more than everyday problems or concerns** (e.g., an occasional argument with family members).
- 81
- 80 **If symptoms are present, they are transient and expectable reactions to psychosocial stressors** (e.g., difficulty concentrating after family argument); **no more than slight impairment in social, occupational, or school functioning** (e.g., temporarily falling behind in schoolwork).
- 71
- 70 **Some mild symptoms** (e.g., depressed mood and mild insomnia) **OR some difficulty in social, occupational, or school functioning** (e.g., occasional truancy, or theft within the household), **but generally functioning pretty well, has some meaningful interpersonal relationships.**
- 61

- 60 **Moderate symptoms** (e.g., flat affect and circumstantial speech, occasional panic attacks) **OR moderate difficulty in social, occupational, or school functioning** (e.g., few friends, conflicts with peers or co-workers).
- 51
- 50 **Serious symptoms** (e.g., suicidal ideation, severe obsessional rituals, frequent shoplifting) **OR any serious impairment in social, occupational, or school functioning** (e.g., no friends, unable to keep a job).
- 41
- 40 **Some impairment in reality testing or communication** (e.g., speech is at times illogical, obscure, or irrelevant) **OR major impairment in several areas, such as work or school, family relations, judgment, thinking, or mood** (e.g., depressed man avoids friends, neglects family, and is unable to work; child frequently beats up younger children, is defiant at home, and is failing at school).
- 31
- 30 **Behavior is considerably influenced by delusions or hallucinations OR serious impairment in communication or judgment** (e.g., sometimes incoherent, acts grossly inappropriately, suicidal preoccupation) **OR inability to function in almost all areas** (e.g., stays in bed all day; no job, home, or friends).
- 21
- 20 **Some danger of hurting self or others** (e.g., suicide attempts without clear expectation of death; frequently violent; manic excitement) **OR occasionally fails to maintain minimal personal hygiene** (e.g., smears feces) **OR gross impairment in communication** (e.g., largely incoherent or mute).
- 11
- 10 **Persistent danger of severely hurting self or others** (e.g., recurrent violence) **OR persistent inability to maintain minimal personal hygiene OR serious suicidal act with clear expectation of death.**
- 1
- 0 Inadequate information.