CITALOPRAM - citalopram capsule
Aurobindo Pharma Limited

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use CITALOPRAM CAPSULES safely and effectively. See full prescribing information for CITALOPRAM CAPSULES.

CITALOPRAM capsules, for oral use
Initial U.S. Approval: 1998

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning.

Increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors (5.1). Citalopram capsules is not approved for use in pediatric patients (8.4).

INDICATIONS AND USAGE

Citalopram capsules is a selective serotonin reuptake inhibitor (SSRI) indicated for treatment of Major Depressive Disorder (MDD) in adults (1).

DOSAGE AND ADMINISTRATION

- Do not initiate treatment with citalopram capsules. Use another citalopram product for initial dosage titration or dosages other than 30 mg once daily (2.1).
- Administer once daily with or without food (2.1).
- Recommended dosage of citalopram capsules is 30 mg once daily (2.1).
- Citalopram dosages above 40 mg once daily are not recommended due to the risk of QT prolongation (2.1).
- When discontinuing citalopram capsules, reduce dose gradually. Gradual dosage reduction will require use of another citalopram product (2.4, 5.6).

DOSAGE FORMS AND STRENGTHS

- Capsules: 30 mg (3)

CONTRAINDICATIONS

- Concomitant use of monoamine oxidase inhibitors (MAOIs) or use within 14 days of discontinuing an MAOI (4).
- Concomitant use of pimozide (4).
- Known hypersensitivity to citalopram or any of the inactive ingredients of citalopram capsules (4).

WARNINGS AND PRECAUTIONS

- *QT Prolongation and Torsade de Pointes*: Dose-dependent QTc prolongation, Torsade de pointes, ventricular tachycardia, and sudden death have occurred. Avoid use of citalopram capsules in patients with congenital long QT syndrome, bradycardia, hypokalemia or hypomagnesemia, recent acute myocardial infarction, or uncompensated heart failure and patients taking other drugs that prolong the QTc interval. Monitor electrolytes in patients at high risk for hypokalemia or hypomagnesemia. Discontinue citalopram capsules in patients with persistent QTc measurements > 500 ms (5.2, 7).
- *Serotonin Syndrome*: Increased risk when co-administered with other serotonergic agents, but also when taken alone. If it occurs, discontinue citalopram capsules and serotonergic agents and initiate supportive treatment (4, 5.3, 7).
- *Increased Risk of Bleeding*: Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs, other antiplatelet drugs, warfarin, and other anticoagulants may increase this risk (5.4).
- *Activation of Mania or Hypomania*: Screen patients for bipolar disorder (5.5).

- *Discontinuation Syndrome*: When discontinuing citalopram capsules, reduce dosage gradually and monitor for discontinuation symptoms. Gradual reduction will require use of another citalopram product (5.6).
- *Seizures*: Use with caution in patients with seizure disorder (5.7).
- *Angle Closure Glaucoma*: Avoid use of citalopram capsules in patients with untreated anatomically narrow angles treated (5.8).
- *Hyponatremia*: Can occur in association with syndrome of inappropriate antidiuretic hormone secretion (5.9).
- *Sexual Dysfunction*: Citalopram capsules may cause symptoms of sexual dysfunction (5.10).

ADVERSE REACTIONS

Most commonly observed adverse reactions (incidence at least twice the incidence of placebo) are: fever, arthalgia, myalgia, anorexia, agitation, yawning, sinusitis, ejaculation disorder (primarily ejaculatory delay), decreased libido, and impotence (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Aurobindo Pharma USA, Inc. at 1-866-850-2876 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- CYP2C19 inhibitors and CYP2C19 poor metabolizers: Avoid concomitant use. There is an increased risk of QT prolongation with concomitant use (7).

USE IN SPECIFIC POPULATIONS

- Pregnancy: SSRI use, particularly late in pregnancy, may increase the risk for persistent pulmonary hypertension and symptoms of poor adaptation (respiratory distress, temperature instability, feeding difficulties, hypotonia, tremor, irritability) in the neonate (8.1).
- Elderly patients: Not recommended (8.5).
- Hepatic Impairment: Not recommended (8.6).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

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FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS
1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
2.1 Recommended Dosage
2.2 Screen for Bipolar Disorder Prior to Starting Citalopram Capsules
2.3 Switching Patients to or from a Monoamine Oxidase Inhibitor Antidepresssant
2.4 Discontinuing Treatment with Citalopram Capsules
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Suicidal Thoughts and Behaviors in Adolescent and Young Adults
5.2 QT-Prolongation and Torsade de Pointes
5.3 Serotonin Syndrome
5.4 Increased Risk of Bleeding
5.5 Activation of Mania or Hypomania
5.6 Discontinuation Syndrome
5.7 Seizures
5.8 Angle Closure Glaucoma
5.9 Hyponatremia
5.10 Sexual Dysfunction

6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
6.2 Post-Marketing Experience
7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Lactation
8.4 Pediatric Use
8.5 Geriatric Use
8.6 Hepatic Impairment
9 DRUG ABUSE AND DEPENDENCE
9.1 Controlled Substance
9.2 Abuse
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
13.2 Animal Toxicology and/or Pharmacology
14 CLINICAL STUDIES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION
* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors *[see Warnings and Precautions (5.1)].* Citalopram capsules is not approved for use in pediatric patients *[see Use in Specific Populations (8.4)].*

1 INDICATIONS AND USAGE

Citalopram capsules are indicated for the treatment of Major Depressive Disorder (MDD) in adults *[see Clinical Studies (14)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Do not initiate treatment with citalopram capsules because the only available dose strength is 30 mg. Use another citalopram product for initial dosage, titration, and dosages other than 30 mg once daily. Refer to Prescribing Information of the other citalopram products for the recommended dosage for those products.

Administer citalopram capsules orally, once daily, with or without food.

Citalopram should be administered at an initial dose of 20 mg once daily, with an increase to a maximum dose of 40 mg once daily at an interval of no less than one week. Citalopram dosages above 40 mg once daily are not recommended due to the risk of QT prolongation *[see Warnings and Precautions (5.2)]*.

2.2 Screen for Bipolar Disorder Prior to Starting Citalopram Capsules

Prior to initiating treatment with citalopram capsules or another antidepressant, screen patients for a personal or family history of bipolar disorder, mania, or hypomania *[see Warnings and Precautions (5.5)]*.

2.3 Switching Patients to or from a Monoamine Oxidase Inhibitor Antidepresssant

At least 14 days must elapse between discontinuation of an monoamine oxidase inhibitor (MAOI) and initiation of therapy with citalopram capsules. Conversely, at least 14 days must elapse after stopping citalopram capsules before starting an MAOI antidepressant *[see Contraindications (4), Warnings and Precautions (5.3)]*.

2.4 Discontinuing Treatment with Citalopram Capsules

Adverse reactions may occur upon discontinuation of citalopram capsules *[see Warnings and Precautions (5.6)]*. Gradually reduce the dosage rather than stopping citalopram capsules abruptly whenever possible. Given that 30 mg is only available dosage strength of citalopram capsules, gradual dosage reduction will require the use of another citalopram product.

3 DOSAGE FORMS AND STRENGTHS

30 mg: White to off-white powder filled in size “3” white opaque cap/white opaque body hard gelatin capsules imprinted with “CL” on cap and “30” on body in black ink.

Citalopram capsules dosage strength is based on the active moiety, citalopram.

4 CONTRAINDICATIONS

Citalopram capsules is contraindicated in patients:

- taking, or within 14 days of stopping, MAOIs (including MAOIs such as linezolid or intravenous methylene blue) because of an increased risk of serotonin syndrome *[see Warnings and Precautions (5.3), Drug Interactions (7)]*.

- taking pimozide because of risk of QT prolongation *[see Drug Interactions (7)]*.
- with known hypersensitivity to citalopram or any of the inactive ingredients in citalopram capsules. Reactions have included angioedema and anaphylaxis *[see Adverse Reactions (6.2)].*

5 WARNINGS AND PRECAUTIONS

5.1 Suicidal Thoughts and Behaviors in Adolescent and Young Adults

In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 77,000 adult patients and over 4,500 pediatric patients, the incidence of suicidal thoughts and behaviors in antidepressant-treated patients age 24 years and younger was greater than in placebo-treated patients. There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied. There were differences in absolute risk of suicidal thoughts and behaviors across the different indications, with the highest incidence in patients with MDD. These drug-placebo differences in the number of cases of suicidal thoughts and behaviors per 1,000 patients treated are provided in Table 1.

Table 1: Risk Differences of the Number of Patients with Suicidal Thoughts or Behavior in the Pooled Placebo-Controlled Trials of Antidepressants in Pediatric* and Adult Patients

Age Range	**Drug-Placebo Difference in Number of Patients* with Suicidal Thoughts or Behaviors per 1,000 Patients Treated**
	Increases Compared to Placebo
<18 years old	14 additional cases
18 to 24 years old	5 additional cases
	Decreases Compared to Placebo
25 to 64 years old	1 fewer case
≥65 years old	6 fewer cases

*Citalopram capsules is not approved for use in pediatric patients.

It is unknown whether the risk of suicidal thoughts and behaviors in children, adolescents, and young adults extends to longer-term use, i.e., beyond four months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with MDD that antidepressants delay the recurrence of depression and that depression itself is a risk factor for suicidal thoughts and behaviors.

Monitor all antidepressant-treated patients for any indication for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy, and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing citalopram

capsules, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

5.2 QT-Prolongation and Torsade de Pointes

Citalopram causes dose-dependent QTc prolongation, an ECG abnormality that has been associated with Torsade de Pointes (TdP), ventricular tachycardia, and sudden death, all of which have been observed in postmarketing reports for citalopram *[see Adverse Reactions 6.2)]*.

Because of the risk of QTc prolongation at higher citalopram doses, it is recommended that citalopram should not be given at doses above 40 mg/day *[see Clinical Pharmacology (12.2)]*.

Avoid use of citalopram capsules in CYP2C19 poor metabolizers, patients receiving concomitant cimetidine or another CYP2C19 inhibitor, patients with hepatic impairment, and patients who are greater than 60 years of age, because citalopram capsules are only available in a 30 mg dose strength and dosage adjustments are not possible *[see Drug Interactions (7), Use in Specific Populations (8.5, 8.6), Clinical Pharmacology (12.3)]*.

Citalopram should be avoided in patients with congenital long QT syndrome, bradycardia, hypokalemia or hypomagnesemia, recent acute myocardial infarction, or uncompensated heart failure unless the benefits outweigh the risks for a particular patient. Citalopram should also not be used in patients who are taking other drugs that prolong the QTc interval *[see Drug Interactions (7)]*. Such drugs include Class 1A (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, antipsychotic medications (e.g., chlorpromazine, thioridazine), antibiotics (e.g., gatifloxacin, moxifloxacin), or any other class of medications known to prolong the QTc interval (e.g., pentamidine, levomethadyl acetate, methadone).

Electrolyte and/or ECG monitoring is recommended in certain circumstances. Patients being considered for citalopram treatment who are at risk for significant electrolyte disturbances should have baseline serum potassium and magnesium measurements with periodic monitoring. Hypokalemia (and/or hypomagnesemia) may increase the risk of QTc prolongation and arrhythmia, and should be corrected prior to initiation of treatment and periodically monitored. ECG monitoring is recommended in patients for whom citalopram use is not recommended unless the benefits clearly outweigh the risks for a particular patient (see above). These include those patients with the cardiac conditions noted above, and those taking other drugs that may prolong the QTc interval.

Discontinue citalopram capsules in patients who are found to have persistent QTc measurements >500 ms. If patients taking citalopram capsules experience symptoms that could indicate the occurrence of cardiac arrhythmias, e.g., dizziness, palpitations, or syncope, the prescriber should initiate further evaluation, including cardiac monitoring.

5.3 Serotonin Syndrome

SSRIs, including citalopram capsules, can precipitate serotonin syndrome, a potentially life-threatening condition. The risk is increased with concomitant use of other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, meperidine, methadone, tryptophan, buspirone, amphetamines, and St. John's Wort) and with drugs that impair metabolism of serotonin, i.e., MAOIs *[see Contraindications (4), Drug Interactions (7)]*. Serotonin syndrome can also occur when these drugs are used alone.

Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea).

The concomitant use of citalopram capsules with MAOIs is contraindicated. In addition, do not initiate citalopram capsules in a patient being treated with MAOIs such as linezolid or intravenous methylene blue. No reports involved the administration of methylene blue by other routes (such as oral tablets or local tissue injection). If it is necessary to initiate treatment with an MAOI such as linezolid or intravenous methylene blue in a patient taking citalopram capsules, discontinue citalopram capsules before initiating treatment with the MAOI *[see Contraindications (4), Drug Interactions (7)].*

Monitor all patients taking citalopram capsules for the emergence of serotonin syndrome. Discontinue treatment with citalopram capsules and any concomitant serotonergic agents immediately if the above symptoms occur, and initiate supportive symptomatic treatment. If concomitant use of citalopram capsules with other serotonergic drugs is clinically warranted, inform patients of the increased risk for serotonin syndrome and monitor for symptoms.

5.4 Increased Risk of Bleeding

Drugs that interfere with serotonin reuptake inhibition, including citalopram capsules, increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDS), antiplatelet drugs, warfarin, and other anticoagulants may add to this risk. Case reports and epidemiological studies (case-control and cohort design) have demonstrated an association between use of drugs that interfere with serotonin reuptake and the occurrence of gastrointestinal bleeding. Based on data from the published observational studies, exposure to SSRIs, particularly in the month before delivery, has been associated with a less than 2-fold increase in the risk of postpartum hemorrhage *[see Use in Specific Populations (8.1)]*. Bleeding events related to drugs that interfere with serotonin reuptake have ranged from ecchymosis, hematoma, epistaxis, and petechiae to life-threatening hemorrhages.

Inform patients about the increased risk of bleeding associated with the concomitant use of citalopram capsules and antiplatelet agents or anticoagulants. For patients taking warfarin, carefully monitor the international normalized ratio *[see Drug Interactions (7)]*.

5.5 Activation of Mania or Hypomania

In patients with bipolar disorder, treating a depressive episode with citalopram capsules

or another antidepressant may precipitate a mixed/manic episode. In controlled clinical trials with another citalopram product, patients with bipolar disorder were excluded; however, symptoms of mania or hypomania were reported in 0.1% of undiagnosed patients treated with the citalopram product. Prior to initiating treatment with citalopram capsules, screen patients for any personal or family history of bipolar disorder, mania, or hypomania *[see Dosage and Administration (2.2)]*.

5.6 Discontinuation Syndrome

Adverse reactions after discontinuation of serotonergic antidepressants, particularly after abrupt discontinuation, include: nausea, sweating, dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesia, such as electric shock sensations), tremor, anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. A gradual reduction in dosage rather than abrupt cessation is recommended whenever possible *[see Dosage and Administration (2.4)]*.

5.7 Seizures

Citalopram has not been systematically evaluated in patients with seizure disorders. Patients with a history of seizures were excluded from clinical studies. In clinical trials of another citalopram product, seizures occurred in 0.3% of patients treated with citalopram (a rate of one patient per 98 years of exposure) and 0.5% of patients treated with placebo (a rate of one patient per 50 years of exposure). Citalopram capsules should be prescribed with caution in patients with a seizure disorder.

5.8 Angle Closure Glaucoma

The pupillary dilation that occurs following use of many antidepressant drugs, including citalopram, may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. Avoid use of antidepressants, including citalopram capsules, in patients with untreated anatomically narrow angles.

5.9 Hyponatremia

Hyponatremia may occur as a result of treatment with SSRIs, including citalopram capsules. Cases with serum sodium lower than 110 mmol/L have been reported with another citalopram product. Signs and symptoms of hyponatremia include headache, difficulty concentrating, memory impairment, confusion, weakness, and unsteadiness, which may lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death. In many cases, this hyponatremia appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

In patients with symptomatic hyponatremia, discontinue citalopram capsules and institute appropriate medical intervention. Elderly patients, patients taking diuretics, and those who are volume depleted may be at greater risk for developing hyponatremia with SSRIs *[see Use in Specific Populations (8.5)]*.

5.10 Sexual Dysfunction

Use of SSRIs, including citalopram capsules, may cause symptoms of sexual dysfunction *[see Adverse Reactions (6.1)]*. In male patients, SSRI use may result in

ejaculatory delay or failure, decreased libido, and erectile dysfunction. In female patients, SSRI use may result in decreased libido and delayed or absent orgasm.

It is important for prescribers to inquire about sexual function prior to initiation of citalopram capsules and to inquire specifically about changes in sexual function during treatment, because sexual function may not be spontaneously reported. When evaluating changes in sexual function, obtaining a detailed history (including timing of symptom onset) is important because sexual symptoms may have other causes, including the underlying psychiatric disorder. Discuss potential management strategies to support patients in making informed decisions about treatment.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Hypersensitivity reactions *[see Contraindications (4)]*
- Suicidal Thoughts and Behaviors in Adolescent and Young Adults *[see Warnings and Precautions (5.1)]*
- QT-Prolongation and Torsade de Pointes *[see Warnings and Precautions (5.2)]*
- Serotonin Syndrome *[see Warnings and Precautions (5.3)]*
- Increased Risk of Bleeding *[see Warnings and Precautions (5.4)]*
- Activation of Mania or Hypomania *[see Warnings and Precautions (5.5)]*
- Discontinuation Syndrome *[see Warnings and Precautions (5.6)]*
- Seizures *[see Warnings and Precautions (5.7)]*
- Angle Closure Glaucoma *[see Warnings and Precautions (5.8)]*
- Hyponatremia *[see Warnings and Precautions (5.9)]*
- Sexual Dysfunction *[see Warnings and Precautions (5.10)]*

6.1 Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

The safety of citalopram capsules for the treatment for major depressive disorder (MDD) in adults is based upon adequate and well-controlled studies of another citalopram product. The results of these adequate and well-controlled studies of citalopram are presented below.

The safety for citalopram included exposures in patients and/or healthy subjects from 3 different groups of studies: 429 healthy subjects in clinical pharmacology/ pharmacokinetic studies; 4,422 exposures from patients in controlled and uncontrolled clinical trials, corresponding to approximately 1,370 patient-exposure years. There were, in addition, over 19,000 exposures from mostly open-label, European postmarketing studies. The conditions and duration of treatment with citalopram varied greatly and included (in overlapping categories) open-label and double-blind studies, inpatient and outpatient studies, fixed-dose and dose-titration studies, and short-term and long-term

exposure.

Adverse Reactions Associated with Discontinuation of Treatment

Among 1,063 patients with MDD who received citalopram at doses ranging from 10 mg to 80 mg once daily in placebo-controlled trials of up to 6 weeks in duration, 16% discontinued treatment due to an adverse reaction, as compared to 8% of 446 patients receiving placebo. The adverse reactions associated with discontinuation (i.e., associated with discontinuation in at least 1% of citalopram-treated patients at a rate at least twice that of placebo) are shown in Table 2.

Table 2: Adverse Reactions Associated with Discontinuation of Treatment in Short-Term, Placebo-Controlled, Depression Trials

Body System/Adverse Reaction	**Citalopram* (N=1,063) %**	**Placebo (N=446) %**
General		
Asthenia	1	<1
Gastrointestinal Disorders		
Nausea	4	0
Dry Mouth	1	<1
Vomiting	1	0
Central and Peripheral Nervous System Disorders		
Dizziness	2	<1
Psychiatric Disorders		
Insomnia	3	1
Somnolence	2	1
Agitation	1	<1

* A patient can report more than one reason for discontinuation and be counted more than once in this table.

Table 3 enumerates adverse reactions that occurred among 1,063 patients with MDD who received citalopram at doses ranging from 10 mg to 80 mg once daily in placebo-controlled trials of up to 6 weeks in duration.

The most common adverse reaction that occurred in citalopram-treated patients with an incidence of 5% or greater and at least twice the incidence in placebo patients was ejaculation disorder (primarily ejaculatory delay) in male patients, see Table 3.

Table 3: Adverse Reactions (≥2% and Greater than Placebo) Among Citalopram-treated Patients*

Body System/Adverse Reaction	**Citalopram (N=1,063) %**	**Placebo (N=446) %**

Gastrointestinal Disorders		
Nausea	21	14
Diarrhea	8	5
Dyspepsia	5	4
Vomiting	4	3
Abdominal Pain	3	2
Autonomic Nervous System Disorders		
Dry Mouth	20	14
Sweating Increased	11	9
Psychiatric Disorders		
Somnolence	18	10
Insomnia	15	14
Anxiety	4	3
Anorexia	4	2
Agitation	3	1
Dysmenorrhea[1]	3	2
Libido Decreased	2	<1
Yawning	2	<1
Central & Peripheral Nervous System Disorders		
Tremor	8	6
Urogenital		
Ejaculation Disorder[2,3]	6	1
Impotence[3]	3	<1
Respiratory System Disorders		
Upper Respiratory Tract Infection	5	4
Rhinitis	5	3
Sinusitis	3	<1
General		
Fatigue	5	3
Fever	2	<1
Musculoskeletal System Disorders		
Arthralgia	2	1
Myalgia	2	1

* Except for the following adverse reactions which had an incidence on placebo. Citalopram: headache, asthenia, dizziness, constipation, palpitation, vision abnormal, sleep disorder, nervousness, pharyngitis, micturition disorder, back pain.

[1] Denominator used was for females only (N=638 citalopram; N=252 placebo).

[2] Primarily ejaculatory delay.

[3] Denominator used was for males only (N=425 citalopram; N=194 placebo).

Dose Dependency of Adverse Reactions

The potential relationship between the dose of citalopram administered and the incidence of adverse reactions was examined in a fixed-dose study in depressed patients receiving

placebo or citalopram 10 mg, 20 mg, 40 mg, and 60 mg (1.5 times the maximum recommended dosage of citalopram). A positive dose response ($p<0.05$) for the following adverse reactions: fatigue, impotence, insomnia, sweating increased, somnolence, and yawning.

Male and Female Sexual Dysfunction with SSRIs

Although changes in sexual desire, sexual performance, and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of SSRI treatment. However, reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance, and satisfaction are difficult to obtain, in part because patients and health care providers may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence.

Table 4 below displays the incidence of sexual side effects reported by at least 2% of male patients taking citalopram in a pool of placebo-controlled clinical trials in patients with depression.

Table 4: Adverse Reactions (≥2%) Related to Sexual Dysfunction in Citalopram-treated Male Patients in Pooled Placebo-Controlled Clinical Trials of MDD

Treatment	**Citalopram**	**Placebo**
n (males)	**425**	**194**
	(%)	**(%)**
Abnormal Ejaculation (mostly ejaculatory delay)	6.1	1
Libido Decreased	3.8	<1
Impotence	2.8	<1

In female depressed patients receiving citalopram, the reported incidence of decreased libido and anorgasmia was 1.3% (n=638 females) and 1.1% (n=252 females), respectively.

Weight Changes

Patients treated with citalopram in controlled trials experienced a weight loss of about 0.5 kg compared to no change for placebo patients.

ECG Changes

In a thorough QT study, citalopram was found to be associated with a dose-dependent increase in the QTc interval.

Electrocardiograms from citalopram (N=802) and placebo (N=241) groups were

compared with respect to outliers defined as subjects with QTc changes over 60 msec from baseline or absolute values over 500 msec post-dose, and subjects with heart rate increases to over 100 bpm or decreases to less than 50 bpm with a 25% change from baseline (tachycardic or bradycardic outliers, respectively). In the citalopram group 1.9% of the patients had a change from baseline in QTcF >60 msec compared to 1.2% of the patients in the placebo group. None of the patients in the placebo group had a post-dose QTcF >500 msec compared to 0.5% of the patients in the citalopram group. The incidence of tachycardic outliers was 0.5% in the citalopram group and 0.4% in the placebo group. The incidence of bradycardic outliers was 0.9% in the citalopram group and 0.4% in the placebo group.

Other Adverse Reactions Observed During the Premarketing Evaluation of Citalopram

The following list of adverse reactions does not include reactions that are: 1) included in Table 3 or elsewhere in labeling, 2) for which a drug cause was remote, 3) which were so general as to be uninformative, and those occurring in only one patient.

Adverse reactions are categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse reactions are those occurring on one or more occasions in at least 1/100 patients; infrequent adverse reactions are those occurring in less than 1/100 patients but at least 1/1000 patients; rare reactions are those occurring in fewer than 1/1000 patients.

Cardiovascular - *Frequent:* tachycardia, postural hypotension, hypotension. *Infrequent:* hypertension, bradycardia, edema (extremities), angina pectoris, extrasystoles, cardiac failure, flushing, myocardial infarction, cerebrovascular accident, myocardial ischemia. *Rare:* transient ischemic attack, phlebitis, atrial fibrillation, cardiac arrest, bundle branch block.

Central and Peripheral Nervous System Disorders - *Frequent:* paresthesia, migraine. *Infrequent:* hyperkinesia, vertigo, hypertonia, extrapyramidal disorder, leg cramps, involuntary muscle contractions, hypokinesia, neuralgia, dystonia, abnormal gait, hypesthesia, ataxia. *Rare:* abnormal coordination, hyperesthesia, ptosis, stupor.

Endocrine Disorders - *Rare:* hypothyroidism, goiter, gynecomastia.

Gastrointestinal Disorders - *Frequent:* saliva increased, flatulence. *Infrequent:* gastritis, gastroenteritis, stomatitis, eructation, hemorrhoids, dysphagia, teeth grinding, gingivitis, esophagitis. *Rare:* colitis, gastric ulcer, cholecystitis, cholelithiasis, duodenal ulcer, gastroesophageal reflux, glossitis, jaundice, diverticulitis, rectal hemorrhage, hiccups.

General - *Infrequent:* hot flushes, rigors, alcohol intolerance, syncope, influenza-like symptoms. *Rare:* hay fever.

Hemic and Lymphatic Disorders - *Infrequent:* purpura, anemia, epistaxis, leukocytosis, leucopenia, lymphadenopathy. *Rare:* pulmonary embolism, granulocytopenia, lymphocytosis, lymphopenia, hypochromic anemia, coagulation disorder, gingival bleeding.

Metabolic and Nutritional Disorders - *Frequent:* decreased weight, increased weight. *Infrequent:* increased hepatic enzymes, thirst, dry eyes, increased alkaline phosphatase, abnormal glucose tolerance. *Rare:* bilirubinemia, hypokalemia, obesity, hypoglycemia, hepatitis, dehydration.

Musculoskeletal System Disorders - *Infrequent:* arthritis, muscle weakness, skeletal pain. *Rare:* bursitis, osteoporosis.

Psychiatric Disorders - *Frequent:* impaired concentration, amnesia, apathy, depression, increased appetite, aggravated depression, suicide attempt, confusion. *Infrequent:* increased libido, aggressive reaction, paroniria, drug dependence, depersonalization, hallucination, euphoria, psychotic depression, delusion, paranoid reaction, emotional lability, panic reaction, psychosis. *Rare:* catatonic reaction, melancholia.

Reproductive Disorders/Female* - *Frequent:* amenorrhea. *Infrequent:* galactorrhea, breast pain, breast enlargement, vaginal hemorrhage. *% based on female subjects only: 2955

Respiratory System Disorders - *Frequent:* coughing. *Infrequent:* bronchitis, dyspnea, pneumonia. *Rare:* asthma, laryngitis, bronchospasm, pneumonitis, sputum increased.

Skin and Appendages Disorders - *Frequent:* rash, pruritus. *Infrequent:* photosensitivity reaction, urticaria, acne, skin discoloration, eczema, alopecia, dermatitis, skin dry, psoriasis. *Rare:* hypertrichosis, decreased sweating, melanosis, keratitis, cellulitis, pruritus ani.

Special Senses - *Frequent:* accommodation abnormal, taste perversion. *Infrequent:* tinnitus, conjunctivitis, eye pain. *Rare:* mydriasis, photophobia, diplopia, abnormal lacrimation, cataract, taste loss.

Urinary System Disorders - *Frequent:* polyuria. *Infrequent:* micturition frequency, urinary incontinence, urinary retention, dysuria. *Rare:* facial edema, hematuria, oliguria, pyelonephritis, renal calculus, renal pain.

6.2 Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of citalopram, the racemate, or escitolapram, the S-entantiomer of citalopram. Because these reactions are reported voluntarily from a population of uncertain size, it is not

always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood and Lymphatic System Disorders: hemolytic anemia, thrombocytopenia, prothrombin decreased

Cardiac Disorders: torsade de pointes, ventricular arrhythmia, QT prolonged

Endocrine Disorders: hyperprolactinemia

Eye Disorders: angle-closure glaucoma

Gastrointestinal Disorders: gastrointestinal hemorrhage, pancreatitis

General Disorders and Administrative Site Conditions: withdrawal syndrome

Hepatobiliary Disorders: hepatic necrosis

Immune System Disorders: anaphylaxis, allergic reaction

Musculoskeletal and Connective Tissue Disorders: rhabdomyolysis

Nervous System Disorders: grand mal convulsion(s), myoclonus, choreoathetosis, dyskinesia, akathisia, nystagmus

Pregnancy, Puerperium and Perinatal Conditions: spontaneous abortion

Psychiatric Disorders: delirium

Renal and Urinary Disorders: acute renal failure

Reproductive System and Breast Disorders: priapism

Respiratory, thoracic and mediastinal disorders: anosmia, hyposmia

Skin and Subcutaneous Tissue Disorders: Stevens Johnson Syndrome, epidermal necrolysis, angioedema, erythema multiforme, ecchymosis

Vascular Disorders: thrombosis

7 DRUG INTERACTIONS

Table 5 presents clinically important drug interactions with citalopram capsules.

Table 5: Clinically Important Drug Interactions with Citalopram Capsules

Monoamine Oxidase Inhibitors (MAOIs)	
Clinical Impact:	Concomitant use of SSRIs, including citalopram capsules, and MAOIs increases the risk of serotonin syndrome.
Intervention:	Citalopram capsules is contraindicated in patients taking MAOIs, including MAOIs such as linezolid or intravenous methylene blue *[see Dosage and Administration (2.3), Contraindications (4), Warnings and Precautions (5.3)]*.
Pimozide	
Clinical Impact:	Concomitant use of citalopram with pimozide increases plasma concentrations of pimozide, a drug with a narrow therapeutic index, and may increase the risk of QT prolongation and/or ventricular arrhythmias

	compared to use of citalopram alone *[see Clinical Pharmacology (12.3)].*
Intervention:	Citalopram capsules is contraindicated in patients taking pimozide *[see Contraindications (4), Warnings and Precautions (5.2)].*
Drugs that Prolong the QTc Interval	
Clinical Impact:	Concomitant use of citalopram with drugs that prolong QT can cause additional QT prolongation compared to the use of citalopram alone *[see Clinical Pharmacology (12.3)].*
Intervention:	Avoid concomitant use of citalopram capsules with drugs that prolong the QT interval (citalopram capsules is contraindicated in patients taking pimozide) *[see Contraindications (4), Warnings and Precautions (5.2)].*
CYP2C19 Inhibitors	
Clinical Impact:	Concomitant use of citalopram with CYP2C19 inhibitors increases the risk of QT prolongation and/or ventricular arrhythmias compared to the use of citalopram alone *[see Clinical Pharmacology (12.3)].*
Intervention:	Avoid concomitant use of citalopram capsules with CYP2C19 inhibitors *[see Warnings and Precautions (5.2)].*
Other Serotonergic Drugs	
Clinical Impact:	Concomitant use of citalopram capsules with other serotonergic drugs (including other SSRIs, SNRIs, triptans, tricyclic antidepressants, opioids, lithium, buspirone, amphetamines, tryptophan, and St. John's Wort) increases the risk of serotonin syndrome.
Intervention:	Monitor patients for signs and symptoms of serotonin syndrome, particularly during citalopram capsules initiation and changes in citalopram dosage. If serotonin syndrome occurs, consider discontinuation of citalopram capsules and/or concomitant serotonergic drugs *[see Dosage and Administration (2.1, 2.4), Warnings and Precautions (5.3)].*
Drugs That Interfere With Hemostasis (antiplatelet agents and anticoagulants)	
Clinical Impact:	Concomitant use of citalopram and an antiplatelet or anticoagulant may potentiate the risk of bleeding.
Intervention:	Inform patients of the increased risk of bleeding associated with the concomitant use of citalopram capsules and antiplatelet agents and anticoagulants. For patients taking warfarin, carefully monitor the international normalized ratio *[see Warnings and Precautions (5.4)].*

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on data from published observational studies, exposure to SSRIs, particularly in the month before delivery, has been associated with a less than 2-fold increase in the risk of postpartum hemorrhage *[see Warnings and Precautions (5.4) and Clinical Considerations]*.

Available data from published epidemiologic studies and postmarketing reports with citalopram use in pregnancy have not established an increased risk of major birth defects or miscarriage. Published studies demonstrated that citalopram levels in both

cord blood and amniotic fluid are similar to those observed in maternal serum. There are risks of persistent pulmonary hypertension of the newborn (PPHN) *(see Data)* and/or poor neonatal adaptation with exposure to selective serotonin reuptake inhibitors (SSRIs), including citalopram capsules, during pregnancy. There also are risks associated with untreated depression in pregnancy *(see Clinical Considerations)*.

In animal reproduction studies, citalopram caused adverse embryo/fetal effects at doses that caused maternal toxicity *(see Data)*.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in the clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Women who discontinue antidepressants during pregnancy are more likely to experience a relapse of major depression than women who continue antidepressants. This finding is from a prospective longitudinal study of 201 pregnant women with a history of major depressive disorder who were euthymic and taking antidepressants at the beginning of pregnancy. Consider the risk of untreated depression when discontinuing or changing treatment with antidepressant medication during pregnancy and postpartum.

Maternal Adverse Reactions

Use of citalopram capsules in the month before delivery may be associated with an increased risk of postpartum hemorrhage *[see Warnings and Precautions (5.4)]*.

Fetal/Neonatal Adverse Reactions

Neonates exposed to citalopram and other SSRIs late in third trimester have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying. These findings are consistent with either a direct toxic effect of SSRIs or possibly, a drug discontinuation syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrome *[see Warnings and Precautions (5.3)]*.

Data

Human Data

Exposure during late pregnancy to SSRIs may have an increased risk for persistent pulmonary hypertension of the newborn (PPHN). PPHN occurs in 1 to 2 per 1,000 live births in the general population and is associated with substantial neonatal morbidity and mortality.

Animal Data

Citalopram was administered orally to pregnant rats during the period of organogenesis at doses of 32, 56, and 112 mg/kg/day, which are approximately 8, 14, and 27 times the Maximum Recommended Human Dose (MRHD) of 40 mg, based on mg/m^2 body surface area. Citalopram caused maternal toxicity of CNS clinical signs and decreased weight gain at 112 mg/kg/day, which is 27 times the MRHD. At this maternally toxic dose, citalopram decreased embryo/fetal growth and survival and increased fetal abnormalities (including cardiovascular and skeletal defects). The no observed adverse effect level (NOAEL) for maternal and embryofetal toxicity is 56 mg/kg/day, which is approximately 14 times the MRHD.

Citalopram was administered orally to pregnant rabbits during the period of organogenesis at doses up to 16 mg/kg/day, which is approximately 8 times the MRHD of 40 mg, based on mg/m^2 body surface area. No maternal or embryofetal toxicity was observed. The NOAEL for maternal and embryofetal toxicity is 16 mg/kg/day, which is approximately 8 times the MRHD.

Citalopram was administered orally to pregnant rats during late gestation and lactation periods at doses of 4.8, 12.8, and 32 mg/kg/day, which are approximately 1, 3, and 8 times the MRHD of 40 mg, based on mg/m^2 body surface area. Citalopram increased offspring mortality during the first 4 days of birth and decreased offspring growth at 32 mg/kg/day, which is approximately 8 times the MRHD. The NOAEL for developmental toxicity is 12.8 mg/kg/day, which is approximately 3 times the MRHD. In a separate study, similar effects on offspring mortality and growth were seen when dams were treated throughout gestation and early lactation at doses ≥ 24 mg/kg/day, which is approximately 6 times the MRHD. A NOAEL was not determined in that study.

8.2 Lactation

Risk Summary

Data from the published literature report the presence of citalopram in human milk at relative infant doses ranging between 0.7 to 9.4% of the maternal weight-adjusted dosage and a milk/plasma ratio ranging between 0.78 to 4.3. There are reports of breastfed infants exposed to citalopram experiencing irritability, restlessness, excessive somnolence, decreased feeding, and weight loss *(see Clinical Considerations).* There is no information about effects of citalopram on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for citalopram capsules and any potential adverse effects on the breastfed child from citalopram capsules or from the underlying maternal condition.

Clinical Considerations

Monitor breastfeeding infants for adverse reactions, such as irritability, restlessness, excessive somnolence, decreased feeding, and weight loss.

8.4 Pediatric Use

The safety and effectiveness of citalopram have not been established in pediatric patients.

Two placebo-controlled trials in 407 pediatric patients with MDD have been conducted with other another formulation of citalopram, and the data were not sufficient to support use in pediatric patients.

Antidepressants increase the risk of suicidal thoughts and behaviors in pediatric patients *[see Boxed Warning, Warnings and Precautions (5.1)]*. Decreased appetite and weight loss have been observed in association with the use of SSRIs in pediatric patients.

8.5 Geriatric Use

Citalopram capsules is not recommended for use in the elderly because dosage adjustments are not possible with the available strengths of citalopram capsules.

In two pharmacokinetic studies, citalopram AUC was increased by 23% and 30%, respectively, in subjects ≥ 60 years of age as compared to younger subjects, and its half-life was increased by 30% and 50%, respectively.

Of 4,422 patients in clinical studies of citalopram, 1357 were 60 and over, 1034 were 65 and over, and 457 were 75 and over.

SSRIs, including citalopram, have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse reaction *[see Warnings and Precautions (5.9)]*.

8.6 Hepatic Impairment

Citalopram capsules is not recommended in patients with hepatic impairment. Citalopram oral clearance was reduced by 37% and half-life was doubled in patients with reduced hepatic function compared to normal subjects *[see Clinical Pharmacology (12.3)].*

Dosage adjustments are not possible with the available strengths of citalopram capsules.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Citalopram is not a controlled substance.

9.2 Abuse

Animal studies suggest that the abuse liability of citalopram is low. Citalopram has not been systematically studied in humans for its potential for abuse, tolerance, or physical dependence. The premarketing clinical experience with citalopram did not reveal any drug-seeking behavior. However, these observations were not systematic and it is not possible to predict, on the basis of this limited experience, the extent to which a CNS-active drug will be misused, diverted, and/or abused once marketed. Consequently, health care providers should carefully evaluate citalopram patients for history of drug abuse and follow such patients closely, observing them for signs of misuse or abuse (e.g., development of tolerance, incrementations of dose, drug-seeking behavior).

10 OVERDOSAGE

The following have been reported with citalopram tablet overdosage:

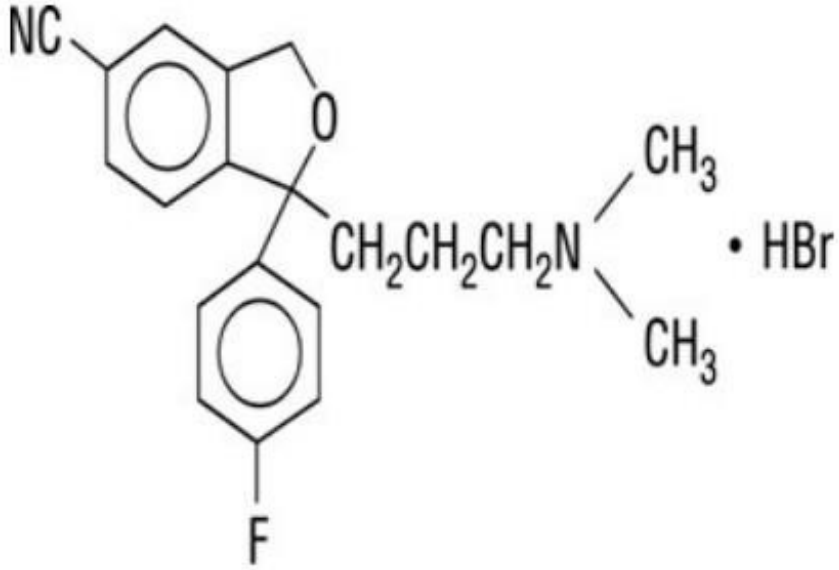
- Seizures, which may be delayed, and altered mental status including coma.
- Cardiovascular toxicity, which may be delayed, including QRS and QTc interval prolongation, wide complex tachyarrhythmias, and torsade de pointes. Hypertension most commonly seen, but rarely can see hypotension alone or with co-ingestants including alcohol.
- Serotonin syndrome (patients with a multiple drug overdosage with other proserotonergic drugs may have a higher risk).

Prolonged cardiac monitoring is recommended in citalopram capsules overdosage ingestions due to the arrhythmia risk. Gastrointestinal decontamination with activated charcoal should be considered in patients who present early after a citalopram capsules overdose.

Consider contacting a Poison Center (1-800-221-2222) or a medical toxicologist for additional overdosage management recommendations.

11 DESCRIPTION

Citalopram capsules contain citalopram, a selective serotonin reuptake inhibitor (SSRI). Citalopram hydrobromide is a racemic bicyclic phthalane derivative designated (±)-1-(3-dimethylaminopropyl)-1-(4-fluorophenyl)-1,3-dihydroisobenzofuran-5carbonitrile, hydrobromide with the following structural formula:



The molecular formula is $C_{20}H_{22}BrFN_2O$ and its molecular weight is 405.35.

Citalopram hydrobromide is a white to almost white crystalline powder. Citalopram hydrobromide is freely soluble in methanol, sparingly soluble in water, in alcohol and in chloroform.

Citalopram capsules is for oral administration and contains 30 mg of citalopram, equivalent to 37.5 mg of citalopram hydrobromide, USP. The strengths reflect citalopram base equivalent content.

Citalopram capsules also contain the inactive ingredients copovidone, corn starch, croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose. The hard gelatin capsule shell contains gelatin and titanium dioxide.

The capsules are imprinted with black ink containing black iron oxide, potassium hydroxide, propylene glycol and shellac.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of citalopram as an antidepressant is unclear, but is presumed to be related to potentiation of serotonergic activity in the central nervous system (CNS) resulting from its inhibition of CNS neuronal reuptake of serotonin (5-HT).

12.2 Pharmacodynamics

In vitro and *in vivo* studies in animals suggest that citalopram is a selective serotonin reuptake inhibitor (SSRI) with minimal effects on norepinephrine (NE) and dopamine (DA) neuronal reuptake.

Citalopram has no or very low affinity for 5-HT1A, 5-HT2A, dopamine D1 and D2, α1-, α2-, and β-adrenergic, histamine H1, gamma aminobutyric acid (GABA), muscarinic cholinergic, and benzodiazepine receptors.

Cardiac Electrophysiology

Individually corrected QTc (QTcNi) interval was evaluated in a randomized, placebo and active (moxifloxacin 400 mg) controlled cross-over, escalating multiple-dose study in 119 healthy subjects. The maximum mean (upper bound of the 95% one-sided confidence interval) difference from placebo were 8.5 (10.8) and 18.5 (21.0) msec for 20 mg and 60 citalopram, respectively. Based on the established exposure-response relationship, the predicted QTcNi change from placebo (upper bound of the 95% one-sided confidence interval) under the Cmax for the dose of 40 mg is 12.6 (14.3) msec *[see Warnings and Precautions (5.2)]*.

12.3 Pharmacokinetics

Biotransformation of citalopram is mainly hepatic, with a mean terminal half-life of about 52.7 hours (30 mg capsule). With once daily dosing, steady state plasma concentrations are achieved within approximately one week. At steady state, the extent of accumulation of citalopram in plasma, based on the half-life, is expected to be 2.5 times the plasma concentrations observed after a single dose.

Absorption

Following a single oral dose (30 mg capsule) of citalopram, peak blood levels occur at about 3.5 hours. The absolute bioavailability of citalopram was about 80% relative to an intravenous dose.

Effect of Food

Administration of citalopram capsules with a high-fat and high calorie breakfast did not have a significant effect on exposure of citalopram. However, median Tmax of citalopram is delayed by approximately 1 hour (6 vs 5 hours).

Distribution

The volume of distribution of citalopram is about 12 L/kg and the binding of citalopram (CT), demethylcitalopram (DCT) and didemethylcitalopram (DDCT) to human plasma proteins is about 80%.

Elimination

Metabolism

Citalopram is metabolized to demethylcitalopram (DCT), didemethylcitalopram (DDCT),

citalopram-N-oxide, and a deaminated propionic acid derivative. In humans, unchanged citalopram is the predominant compound in plasma. At steady state, the concentrations of citalopram's metabolites, DCT and DDCT, in plasma are approximately one-half and one-tenth, respectively, that of the parent drug. *In vitro* studies show that citalopram is at least 8 times more potent than its metabolites in the inhibition of serotonin reuptake, suggesting that the metabolites evaluated do not likely contribute significantly to the antidepressant actions of citalopram.

In vitro studies using human liver microsomes indicated that CYP3A4 and CYP2C19 are the primary isozymes involved in the N-demethylation of citalopram.

Excretion

Following intravenous administrations of citalopram, the fraction of drug recovered in the urine as citalopram and DCT was about 10% and 5%, respectively. The systemic clearance of citalopram was 330 mL/min, with approximately 20% of that due to renal clearance.

Specific Populations

Geriatric Patients

Citalopram pharmacokinetics in subjects 60 years of age were compared to younger subjects in two normal volunteer studies. In a single-dose study, citalopram AUC and half-life were increased in the subjects 60 years old by 30% and 50%, respectively, whereas in a multiple-dose study they were increased by 23% and 30%, respectively *[see Warnings and Precautions (5.2), Use in Specific Populations (8.5)].*

Male and Female Patients

In three pharmacokinetic studies (total N=32), citalopram AUC in women was one and a half to two times that in men. This difference was not observed in five other pharmacokinetic studies (total N=114). In clinical studies, no differences in steady state serum citalopram levels were seen between men (N=237) and women (N=388). There were no gender differences in the pharmacokinetics of DCT and DDCT.

Patients with Hepatic Impairment

Citalopram oral clearance was reduced by 37% and half-life was doubled in patients with reduced hepatic function compared to normal subjects *[see Warnings and Precautions (5.2)]*.

Patients with Renal Impairment

In patients with mild to moderate renal impairment, oral clearance of citalopram was reduced by 17% compared to normal subjects. No adjustment of dosage for such patients is recommended. No information is available about the pharmacokinetics of citalopram in patients with severe renal impairment (creatinine clearance < 20 mL/min).

CYP2C19 Poor Metabolizers

In CYP2C19 poor metabolizers, citalopram steady state Cmax and AUC was increased by 68% and 107%, respectively *[see Warnings and Precautions (5.2)]*.

CYP2D6 Poor Metabolizers

Citalopram steady state levels were not significantly different in poor metabolizers and extensive metabolizers of CYP2D6.

Drug Interaction Studies

In vitro enzyme inhibition data did not reveal an inhibitory effect of citalopram on CYP3A4, -2C9, or -2E1, but did suggest that it is a weak inhibitor of CYP1A2, -2D6, and -2C19. Citalopram would be expected to have little inhibitory effect on *in vivo* metabolism mediated by these enzymes. However, *in vivo* data to address this question are limited.

CYP3A4 and CYP2C19 Inhibitors

Since CYP3A4 and CYP2C19 are the primary enzymes involved in the metabolism of citalopram, it is expected that potent inhibitors of CYP3A4 (e.g., ketoconazole, itraconazole, and macrolide antibiotics) and inhibitors of CYP2C19 (e.g., omeprazole, cimetidine) might decrease the clearance of citalopram. However, coadministration of citalopram and the potent CYP3A4 inhibitor ketoconazole did not significantly affect the pharmacokinetics of citalopram *[see Warnings and Precautions (5.2), Drug Interactions (7)]*.

Cimetidine

In subjects who had received 21 days of 40 mg/day citalopram, combined administration of 400 mg twice a day cimetidine for 8 days resulted in an increase in citalopram AUC and Cmax of 43% and 39%, respectively *[see Warnings and Precautions (5.2), Drug Interactions (7)]*.

CYP2D6 Inhibitors

Coadministration of a drug that inhibits CYP2D6 with citalopram is unlikely to have clinically significant effects on citalopram metabolism, based on the study results in CYP2D6 poor metabolizers.

Digoxin

In subjects who had received 21 days of 40 mg/day citalopram, combined administration of citalopram and digoxin (single dose of 1 mg) did not significantly affect the pharmacokinetics of either citalopram or digoxin.

Lithium

Coadministration of citalopram (40 mg/day for 10 days) and lithium (30 mmol/day for 5 days) had no significant effect on the pharmacokinetics of citalopram or lithium.

Pimozide

In a controlled study, a single dose of pimozide 2 mg co-administered with citalopram 40 mg given once daily for 11 days was associated with a mean increase in QTc values of approximately 10 msec compared to pimozide given alone. Citalopram did not alter the mean AUC or Cmax of pimozide. The mechanism of this pharmacodynamic interaction is not known *[see Contraindications (4), Warnings and Precautions (5.2)]*.

Theophylline

Combined administration of citalopram (40 mg/day for 21 days) and the CYP1A2 substrate theophylline (single dose of 300 mg) did not affect the pharmacokinetics of theophylline. The effect of theophylline on the pharmacokinetics of citalopram was not evaluated.

Warfarin

Administration of 40 mg/day citalopram for 21 days did not affect the pharmacokinetics of warfarin, a CYP3A4 substrate. Prothrombin time was increased by 5%, the clinical significance of which is unknown.

Carbamazepine

Combined administration of citalopram (40 mg/day for 14 days) and carbamazepine (titrated to 400 mg/day for 35 days) did not significantly affect the pharmacokinetics of carbamazepine, a CYP3A4 substrate. Although trough citalopram plasma levels were unaffected, given the enzyme-inducing properties of carbamazepine, the possibility that carbamazepine might increase the clearance of citalopram should be considered if the two drugs are coadministered.

Triazolam

Combined administration of citalopram (titrated to 40 mg/day for 28 days) and the CYP3A4 substrate triazolam (single dose of 0.25 mg) did not significantly affect the pharmacokinetics of either citalopram or triazolam.

Ketoconazole

Combined administration of citalopram (40 mg) and ketoconazole (200 mg) decreased the C_{max} and AUC of ketoconazole by 21% and 10%, respectively, and did not significantly affect the pharmacokinetics of citalopram.

Metoprolol

Administration of 40 mg/day citalopram for 22 days resulted in a two-fold increase in the plasma levels of the beta-adrenergic blocker metoprolol. Increased metoprolol plasma levels have been associated with decreased cardioselectivity. Coadministration of

citalopram and metoprolol had no clinically significant effects on blood pressure or heart rate.

Imipramine and Other Tricyclic Antidepressants (TCAs)

In vitro studies suggest that citalopram is a relatively weak inhibitor of CYP2D6. Coadministration of citalopram (40 mg/day for 10 days) with the TCA imipramine (single dose of 100 mg), a substrate for CYP2D6, did not significantly affect the plasma concentrations of imipramine or citalopram. However, the concentration of the imipramine metabolite desipramine was increased by approximately 50%. The clinical significance of the desipramine change is unknown.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Citalopram increased the incidence of small intestine carcinoma in rats treated for 24 months at doses of 8 and 24 mg/kg/day in the diet, which are approximately 2 and 6 times the Maximum Recommended Human Dose (MRHD) of 40 mg, respectively, based on mg/m^2 body surface area. A no-effect level (NOEL) for this finding was not established.

Citalopram did not increase the incidence of tumors in mice treated for 18 months at doses up 240 mg/kg/day in the diet, which is approximately 30 times the MRDH of 40 mg based on mg/m^2 body surface area.

Mutagenesis

Citalopram was mutagenic in the *in vitro* bacterial reverse mutation assay (Ames test) in 2 of 5 bacterial strains (Salmonella TA98 and TA1537) in the absence of metabolic activation. It was clastogenic in the *in vitro* Chinese hamster lung cell assay for chromosomal aberrations in the presence and absence of metabolic activation. Citalopram was not mutagenic in the *in vitro* mammalian forward gene mutation assay (HPRT) in mouse lymphoma cells or in *in vitro/in vivo* unscheduled DNA synthesis (UDS) assay in rat liver. It was not clastogenic in the *in vitro* chromosomal aberration assay in human lymphocytes or in two *in vivo* mouse micronucleus assays.

Impairment of Fertility

Citalopram was administered orally to female and male rats at doses of 32, 48, and 72 mg/kg/day prior to and throughout mating and continuing to gestation. These doses are approximately 8, 12, and 17 times the MRHD of 40 mg based on mg/m^2 body surface area. Mating and fertility were decreased at doses ≥ 32 mg/kg/day, which is approximately 8 times the MRHD. Gestation duration was increased at 48 mg/kg/day,

which is approximately 12 times the MRHD.

13.2 Animal Toxicology and/or Pharmacology

Retinal Changes in Rats

Pathologic changes (degeneration/atrophy) were observed in the retinas of albino rats in the 2-year carcinogenicity study with citalopram. There was an increase in both incidence and severity of retinal pathology in both male and female rats receiving 80 mg/kg/day, which is approximately 19 times the MRHD of 40 mg based on mg/m^2 body surface area. Similar findings were not present in rats treated for two years at the dose of 24 mg/kg/day, in mice treated for 18 months at doses up to 240 mg/kg/day, or in dogs treated for one year at doses up to 20 mg/kg/day, which are approximately 6, 29, and 17 times the MRHD, respectively, based on mg/m^2 body surface area.

Additional studies to investigate the mechanism for this pathology have not been performed, and the potential significance of this effect in humans has not been established.

14 CLINICAL STUDIES

The efficacy of citalopram capsules for the treatment for major depressive disorder (MDD) in adult patients is based upon adequate and well-controlled studies of another citalopram product. The results of these adequate and well-controlled studies of citalopram are presented below.

The efficacy of citalopram was established in two placebo-controlled studies (of 4 to 6 weeks in duration) in adult outpatients (ages 18 to 66) meeting DSM-III or DSM-III-R criteria for major depression (Studies 1 and 2).

Study 1, a 6-week trial in which patients received fixed citalopram doses of 10 mg, 20 mg, 40 mg, and 60 mg daily, showed that citalopram at doses of 40 mg and 60 mg daily (1.5 times the maximum recommended daily dosage of citalopram) was effective as measured by the Hamilton Depression Rating Scale (HAMD) total score, the primary efficacy endpoint. The HAMD-17 is a 17-item, clinician-rated scale used to assess severity of depressive symptoms. Scores on the HAMD-17 range from 0 to 52, with higher scores indicating more severe depression. This study showed no clear effect of the 10 mg and 20 mg daily doses, and the 60 mg daily dose was not more effective than the 40 mg daily dose. Due to the risk of QTc prolongation and ventricular arrhythmias, the maximum recommended dosage of citalopram is 40 mg once daily.

In study 2, a 4-week, placebo-controlled trial in patients with MDD, the initial dose was 20 mg daily, followed by titration to the maximum tolerated dose or a maximum dose of 80 mg daily (2 times the recommended daily dosage of citalopram). Patients treated with citalopram showed significantly greater improvement than placebo patients on the HAMD total score, the primary efficacy endpoint. In three additional placebo-controlled trials in patients with MDD, the difference in response to treatment between patients

receiving citalopram and patients receiving placebo was not statistically significant.

In two long-term studies, patients with MDD who had responded to citalopram during an initial 6 or 8 weeks of acute treatment were randomized to continuation of citalopram or placebo. In one study, patients received fixed doses of citalopram 20 mg or 40 mg daily and in the second study, patients received flexible doses of citalopram 20 mg to 60 mg daily (1.5 times the maximum recommended daily dosage for citalopram). In both studies, patients receiving continued citalopram treatment experienced statistically significantly lower relapse rates over the subsequent 6 months compared to those receiving placebo. In the fixed-dose study, the decreased rate of depression relapse was similar in patients receiving 20 mg or 40 mg daily of citalopram. Due to the risk of QTc prolongation and ventricular arrhythmias, the maximum recommended dosage of citalopram is 40 mg once daily.

Analyses of the relationship between treatment outcome and age, gender, and race did not suggest any differential responsiveness on the basis of these patient characteristics.

16 HOW SUPPLIED/STORAGE AND HANDLING

Citalopram capsules are supplied as:

30 mg capsules: White to off-white powder filled in size “3” white opaque cap/white opaque body hard gelatin capsules imprinted with “CL” on cap and “30” on body in black ink.

NDC 59651-964-30 Bottle of 30 capsules

Storage and Handling

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Suicidal Thoughts and Behaviors

Advise patients, and caregivers to look for the emergence of suicidality, especially during treatment and when the dose is adjusted up or down, and instruct them to report such symptoms to their healthcare provider *[see Boxed Warning and Warnings and Precautions (5.1)]*.

QTc Prolongation and Torsade de Pointes

Advise patients to consult their healthcare provider immediately if they feel faint, lose consciousness, or have heart palpitations. Instruct patients to inform their healthcare provider that they are taking citalopram capsules before taking any new medications *[see Warnings and Precautions (5.2)]*.

Serotonin Syndrome

Caution patients about the risk of serotonin syndrome, particularly with the concomitant use of citalopram capsules with other serotonergic drugs including triptans, tricyclic antidepressants, opioids, lithium, amphetamines, tryptophan, buspirone, St. John's Wort, and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid). Instruct patients to contact their health care provider or report to the emergency room if they experience signs or symptoms of serotonin syndrome *[see Warnings and Precautions (5.3), Drug Interactions (7)]*.

Increased Risk of Bleeding

Inform patients about the concomitant use of citalopram capsules with aspirin, NSAIDs, other antiplatelet drugs, warfarin, or other anticoagulants because the combined use has been associated with an increased risk of bleeding. Advise patients to inform their health care provider if they are taking or are planning to take any prescription or over-the-counter medications that increase the risk of bleeding *[see Warnings and Precautions (5.4)]*.

Activation of Mania or Hypomania

Advise patients and their caregivers to observe for signs of activation of mania/hypomania and instruct them to report such symptoms to the healthcare provider *[see Warnings and Precautions (5.5)]*.

Discontinuation Syndrome

Advise patients not to abruptly discontinue citalopram capsules and to discuss any tapering regimen with their healthcare provider. Inform patients that adverse reactions can occur when citalopram capsules is discontinued *[see Warnings and Precautions (5.6)].*

Sexual Dysfunction

Advise patients that use of citalopram capsules may cause symptoms of sexual dysfunction in both male and female patients. Inform patients that they should discuss any changes in sexual function and potential management strategies with their healthcare provider *[see Warnings and Precautions (5.10)]*.

Pregnancy

- Advise pregnant women to notify their healthcare providers if they become pregnant or intend to become pregnant during treatment with citalopram capsules.
- Advise patients that citalopram capsules use late in pregnancy may lead to an increased risk for neonatal complications requiring prolonged hospitalization, respiratory support, tube feeding, and/or persistent pulmonary hypertension of the newborn (PPHN) *[see Use in Specific Populations (8.1)]*.

Lactation

Advise breastfeeding women to monitor infants for excess sedation, restlessness, agitation, poor feeding and poor weight gain and to seek medical care if they notice these signs *[see Use in Specific Populations (8.2)]*.

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Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Manufactured by:
Aurobindo Pharma Limited
Hyderabad-500 032, India

Revised: 09/2025

MEDICATION GUIDE
Citalopram (sye tal' oh pram)
Capsules
for oral use

What is the most important information I should know about citalopram capsules?
Citalopram capsules may cause serious side effects, including:

- **Increased risk of suicidal thoughts and actions.** Citalopram capsules and other antidepressant medicines may increase suicidal thoughts and actions in some children, adolescents, and young adults, **especially within the first few months of treatment or when the dose is changed. Citalopram capsules is not for use in children.**
  - Depression or other mental illnesses are the most important causes of suicidal thoughts and actions.

How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions. This is very

important when an antidepressant medicine is started or when the dose is changed.
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call your healthcare provider or get emergency help right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:
- thoughts about suicide or dying
- new or worse depression
- feeling very agitated or restless
- trouble sleeping (insomnia)
- acting aggressive, being angry, or violent
- an extreme increase in activity and (mania)
- attempts to commit suicide
- new or worse anxiety
- panic attacks
- new or worse irritability
- acting on dangerous impulses
- other unusual changes in behavior or mood

What is citalopram capsules?

Citalopram capsules is a prescription medicine used to treat a certain type of depression called Major Depressive Disorder (MDD) in adults.

It is not known if citalopram capsules is safe and effective for use in children.

Who should not take citalopram capsules?
Do not take citalopram capsules if you:
- take a Monoamine Oxidase Inhibitor (MAOI)
- have stopped taking an MAOI in the last 14 days
- are being treated with the antibiotic linezolid or intravenous methylene blue
- take pimozide
- are allergic to citalopram or any of the ingredients in citalopram capsules. See the end of this Medication Guide for a complete list of ingredients in citalopram capsules.

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including MAOIs such as linezolid or intravenous methylene blue.

Do not start taking an MAOI for at least 14 days after you stop treatment with citalopram capsules.

Before taking citalopram capsules, tell your healthcare provider about all your medical conditions, including if you:
- have or had a family history of suicide, depression, bipolar disorder, mania or hypomania
- have an abnormal heart rhythm called QT prolongation
- have or had heart problems, including a heart attack, heart failure, abnormal heart

rhythm, or long QT syndrome
- have low potassium, magnesium, or sodium levels in your blood
- have or had bleeding problems
- have or had seizures (convulsions)
- have high pressure in the eye (glaucoma)
- have or had kidney or liver problems
- are pregnant or plan to become pregnant. Citalopram capsules may harm your unborn baby. Taking citalopram capsules late in pregnancy may lead to an increased risk of certain problems in your newborn. Talk to your healthcare provider about the risks and benefits of treating depression during pregnancy.
  - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with citalopram capsules.
- are breastfeeding or plan to breastfeed. Citalopram passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with citalopram capsules.
  - If you breastfeed during treatment with citalopram capsules, tell your healthcare provider right away if your baby develops sleepiness or fussiness, or is not feeding or gaining weight well.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Citalopram capsules and other medicines may affect each other causing possible serious side effects. Citalopram capsules may affect the way other medicines work and other medicines may affect the way citalopram capsules works.

Especially tell your healthcare provider if you take:
- medicines used to treat migraine headaches known as triptans
- tricyclic antidepressants
- lithium
- tramadol, fentanyl, meperidine, methadone, or other opioids
- tryptophan
- buspirone
- amphetamines
- St. John’s Wort
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs) and warfarin
- diuretics
- methadone
- gatifloxacin or moxifloxacin
- medicines used to control your heart rate or rhythm (antiarrhythmics)
- medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take citalopram capsules with your other medicines.

Do not start or stop any other medicines during treatment with citalopram capsules without talking to your healthcare provider first. Stopping citalopram capsules suddenly may cause you to have serious side effects. See, "**What are the possible side effects of citalopram capsules?"**

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take citalopram capsules?

- Take citalopram capsules exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking citalopram capsules without first talking to your healthcare provider.
- Your healthcare provider may need to change the dose of citalopram capsules until it is the right dose for you.
- Take citalopram capsules 1 time each day with or without food.
- If you take too much citalopram capsules, call your healthcare provider or poison control center at 1-800-222- 1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of citalopram capsules?
Citalopram capsules may cause serious side effects, including:

- See **"What is the most important information I should know about citalopram capsules?"**
- **Heart rhythm problems.** Citalopram capsules may cause a serious change in your heartbeat (a fast or irregular heartbeat) that may cause death. Tell your healthcare provider right away if you feel faint or pass out, or if you have a change in your heartbeat.
- **Serotonin syndrome.** Taking citalopram capsules can cause a potentially life-threatening problem called serotonin syndrome. The risk of developing serotonin syndrome is increased when citalopram capsules is taken with certain other medicines. See, **"Who should not take citalopram capsules?" Call your healthcare provider or go to the nearest hospital emergency room right away** if you have any of the following signs and symptoms of serotonin syndrome:
  - agitation
  - Seeing or hearing things that are not real (hallucinations)
  - confusion
  - coma
  - fast heartbeat
  - blood pressure changes
  - dizziness
  - sweating
  - flushing
  - high body temperature (hyperthermia)
  - tremors, stiff muscles, or muscle twitching
  - loss of coordination
  - seizures
  - nausea, vomiting, diarrhea

- **Increased risk of bleeding.** Taking citalopram capsules with aspirin, non-steroidal

anti-inflammatory drugs (NSAIDs), warfarin or blood thinners may add to this risk. Tell your healthcare provider right away about any unusual bleeding or bruising.

- **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take citalopram capsules. **Symptoms may include:**
  - greatly increased energy
  - severe trouble sleeping
  - racing thoughts
  - reckless behavior
  - unusually grand ideas
  - excessive happiness or irritability
  - talking more or faster than usual

- **Discontinuation syndrome**. Suddenly stopping citalopram capsules may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:
  - nausea
  - changes in your mood
  - irritability and agitation
  - dizziness
  - electric shock sensation (paresthesia)
  - anxiety
  - confusion
  - sweating
  - headache
  - tiredness
  - problems sleeping
  - hypomania
  - ringing in your ears (tinnitus)
  - seizures

- **Seizures (convulsions).**
- **Eye problems (angle-closure glaucoma).** Many antidepressant medicines, including citalopram capsules, may cause a certain type of eye problem called angle-closure glaucoma. Call your healthcare provider if you have changes in your vision or eye pain.
- **Low sodium levels in your blood (hyponatremia).** Low sodium levels in your blood may be serious and may cause death. Elderly people may be at greater risk for this. Tell your healthcare provider right away if you develop any signs or symptoms of low sodium levels in your blood during treatment with citalopram capsules. Signs and symptoms of low sodium levels in your blood may include:
  - headache
  - memory changes
  - weakness and unsteadiness on your feet which can lead to falls
  - difficulty concentrating
  - confusion

In severe or more sudden cases, signs and symptoms include:

- hallucinations (seeing or hearing things that are not real)
- seizures

- stopping breathing
- fainting
- coma
- death

- **Sexual problems (dysfunction).** Taking selective serotonin reuptake inhibitors (SSRIs), including citalopram capsules, may cause sexual problems that are common but may be serious.

Symptoms in males may include:
- Delayed ejaculation or inability to have an ejaculation
- Decreased sex drive
- Problems getting or keeping an erection

Symptoms in females may include:
- Decreased sex drive
- Delayed orgasm or inability to have an orgasm

Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with citalopram capsules. There may be treatments your healthcare provider can suggest.

The most common side effects of citalopram capsules include:

- fever
- joint stiffness
- muscle aches and pain
- not feeling hungry (anorexia)
- agitation
- yawning
- swelling of your sinuses

These are not all the possible side effects of citalopram capsules.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store citalopram capsules?
- Store citalopram capsules at room temperature between 20° to 25°C (68° to 77°F).
- **Keep citalopram capsules and all medicines out of the reach of children.**

General information about the safe and effective use of citalopram capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use citalopram capsules for a condition for which it was not prescribed. Do not give citalopram capsules to other people, even if they have the same symptoms that you have. It may harm them. You may ask your healthcare provider or pharmacist for information about citalopram capsules that is written for healthcare professionals.

What are the ingredients in citalopram capsules?

Active ingredient: citalopram hydrobromide

Inactive ingredients: copovidone, corn starch, croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose. The hard gelatin capsule shell contains gelatin and titanium dioxide.

The capsules are imprinted with black ink containing black iron oxide, potassium hydroxide, propylene glycol and shellac.

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For more information about citalopram capsules, call 1-866-850-2876

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: 09/2025

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 30 mg (30 Capsules Bottle)

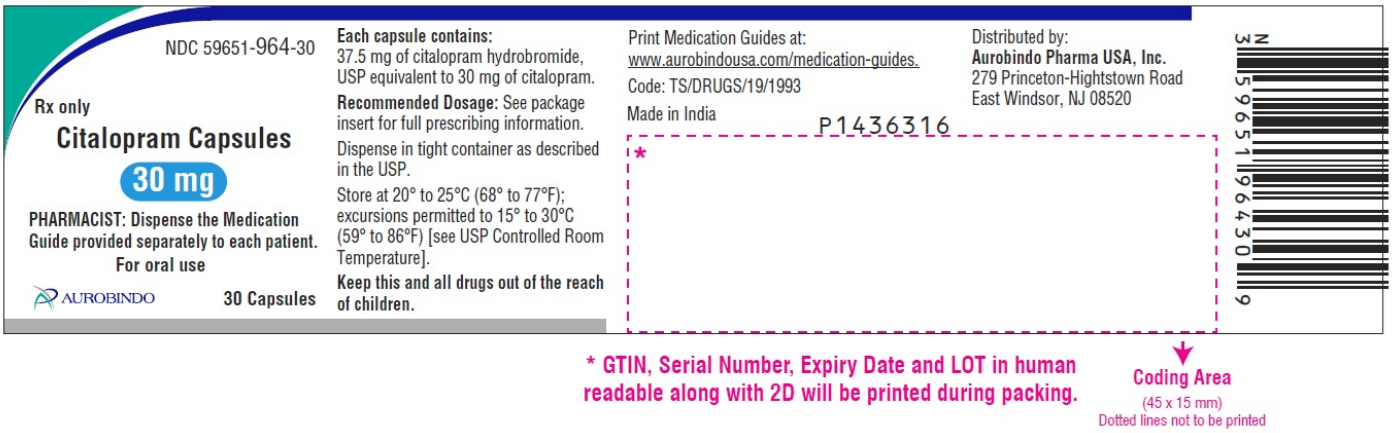
NDC 59651-964-30

Rx only

Citalopram Capsules
30 mg

PHARMACIST: Dispense the Medication
Guide provided separately to each patient.
For oral use

AUROBINDO 30 Capsules



CITALOPRAM

citalopram capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59651-964
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CITALOPRAM HYDROBROMIDE (UNII: I1E9D14F36) (CITALOPRAM - UNII:0DHU5B8D6V)	CITALOPRAM	30 mg

Inactive Ingredients	
Ingredient Name	**Strength**
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics			
Color	WHITE (White to off-white)	**Score**	no score

Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	CL;30
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59651-964-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/13/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA219985	03/13/2026	

Labeler - Aurobindo Pharma Limited (650082092)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(59651-964) , MANUFACTURE(59651-964)

Revised: 3/2026 Aurobindo Pharma Limited