Suicidality and Antidepressant Drugs

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Citalo or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Citalo is not approved for use in pediatric patients.

Citalo

(citalopram hydroromide) 20mg, 40mg film coated tablets/oral solution 2mg/ml.

COMPOSITION:

Active ingredients:

Citalo 20mg film coated tablets:
each film coated tablet contains Citalopram Hydrobromide equivalent to 20 mg Citalopram.

Citalo 40mg film coated tablets:
each film coated tablet contains Citalopram Hydrobromide equivalent to 40 mg Citalopram.

Inactive ingredients:

Citalo 20mg film coated tablets: Lactose monohydrate, Microcrystalline Cellulose pH 102, Colloidal Silicon Dioxide (Aerosil 200), Magnesium Stearate, Croscarmellose Sodium.

Citalo 40mg film coated tablets:
Lactose monohydrate D.C., Microcrystalline Cellulose pH 102, Colloidal Silicon Dioxide (Aerosil 200), Magnesium Stearate, Croscarmellose Sodium.

Coat: Hydroxypropylmethyl Cellulose 2910, Titanium Dioxide, Polyethylene Glycol 6000.

Citalo oral solution:

Active ingredient: each 1ml contains citalopram hydrobromide equivalent to 2mg citalopram.

Inactive ingredients: methyl paraben, propyl paraben, sorbitol 70%, propylene glycol 400, saccharine sodium, banana flavor powder 212004, citric acid, purified water.

CLINICAL PHARMACOLOGY

Pharmacodynamics

The mechanism of action of citalopram HBr as an antidepressant is presumed to be linked to potentiation of serotonergic activity in the central nervous system (CNS) resulting from its inhibition of CNS neuronal reuptake of serotonin (5-HT). In vitro and in vivo studies in animals suggest that citalopram is a highly selective serotonin reuptake inhibitor (SSRI) with minimal effects on norepinephrine (NE) and dopamine (DA) neuronal reuptake. Tolerance to the inhibition of 5-HT uptake is not induced by long-term (14-day) treatment of rats with citalopram.

Citalopram is a racemic mixture (50/50), and the inhibition of 5-HT reuptake by citalopram is primarily due to the (S)-enantiomer. Citalopram has no or very low affinity for 5-HT1A, adrenergic, 5-HT2A, dopamine D1 and D2, α1-, α2-, and β-adrenergic, histamine H1, gamma aminobutyric acid (GABA), muscarinic cholinergic, and benzodiazepine receptors. Antagonism of muscarinic, histaminergic, and adrenergic receptors has been hypothesized to be associated with various anticholinergic, sedative, and cardiovascular effects of other psychotropic drugs.

Pharmacokinetics

The single- and multiple-dose pharmacokinetics of citalopram are linear and dose-proportional in a dose range of 10-60 mg/day. Biotransformation of citalopram is mainly hepatic, with a mean terminal half-life of about 35 hours. 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. The tablet and oral solution dosage forms of citalopram HBr are bioequivalent.

Absorption and Distribution

Following a single oral dose (40 mg tablet) of citalopram, peak blood levels occur at about 4 hours. The absolute bioavailability of citalopram was about 80% relative to an intravenous dose, and absorption is not affected by food. 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%.

Metabolism and Elimination

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.

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.

Population Subgroups

Age - Citalopram pharmacokinetics in subjects $\geq$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 $\geq$ 60 years old by 30% and 50%, respectively, whereas in a multiple-dose study they were increased by 23% and 30%, respectively. 20 mg/day is the maximum recommended dose for patients who are greater than 60 years of age (see **WARNINGS** and **DOSAGE AND ADMINISTRATION**), due to the risk of QT prolongation.

Reduced hepatic function: Citalopram oral clearance was reduced by 37% and half-life was doubled in patients with reduced hepatic function compared to normal subjects. 20 mg/day is the maximum recommended dose for hepatically impaired patients due to the risk of QT prolongation.

CYP2C19 poor metabolizers: In CYP2C19 poor metabolizers, citalopram steady state Cmax and AUC was increased by 68% and 107%, respectively.

Citalo 20 mg/day is the maximum recommended dose in CYP2C19 poor metabolizers due to the risk of QT prolongation.

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

Reduced renal function :

In patients with mild to moderate renal function 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 severely reduced renal function (creatinine clearance < 20 mL/min).

Drug-Drug Interactions

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 CYP 2C19 inhibitors: Since CYP3A4 and CYP 2C19 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 potent inhibitors of CYP2C19 (e.g., omeprazole) might decrease the clearance of citalopram. However, coadministration of citalopram and the potent CYP3A4 inhibitor ketoconazole did not significantly affect the pharmacokinetics of citalopram. Citalo 20 mg/day is the maximum recommended dose in patients taking concomitant cimetidine or another CYP2C19 inhibitor, because of the risk of QT prolongation.

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

INDICATIONS AND USAGE

Citalo (citalopram hydrobromide) is indicated for the treatment of depression.

Citalo (citalopram hydrobromide) is also indicated in the treatment of panic disorder with or without agoraphobia.

CONTRAINDICATIONS

- The use of MAOIs intended to treat psychiatric disorders with Citalo or within 14 days of stopping treatment with Citalo is contraindicated because of an increased risk of serotonin syndrome.
- The use of Citalo within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated.
- Starting Citalo in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome.
- Concomitant use in patients taking pimozide is contraindicated.
- Citalo is contraindicated in patients with a hypersensitivity to citalopram or any of the inactive ingredients in Citalo.
- Do not use citalopram with other medicinal products known to prolong the QT interval.
- Citalopram is contraindicated in patients with congenital QT syndrome.

WARNINGS

WARNINGS-Clinical Worsening and Suicide Risk

•Clinical Worsening and Suicide Risk

Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment.

It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance trials in adults with depression that the use of antidepressants can delay the recurrence of depression.

All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric.

Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality.

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

If the decision has been made to discontinue treatment, medication should be tapered, as rapidly as is feasible, but with recognition that abrupt discontinuation can be associated with certain symptoms.

Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for Citalo should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

•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 post-marketing reports for citalopram.

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.

It is recommended that citalopram should not be used in patients with congenital long QT syndrome, bradycardia, hypokalemia or hypomagnesemia, recent acute myocardial infarction, or uncompensated heart failure. Citalopram should also not be used in patients who are taking other drugs that prolong the QTc interval. 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).

The citalopram dose should be limited in certain populations. The maximum dose should be limited to 20 mg/day in patients who are CYP2C19 poor metabolizers or those patients who may be taking concomitant cimetidine or another CYP2C19 inhibitor, since higher citalopram exposures would be expected. The maximum dose should also be limited to 20 mg/day in patients with hepatic impairment and in patients who are greater than 60 years of age because of expected higher exposures.

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 (see above), but, nevertheless, considered essential. These include those patients with the cardiac conditions noted above, and those taking other drugs that may prolong the QTc interval.

Citalopram should be discontinued in patients who are found to have persistent QTc measurements >500 ms. If patients taking citalopram 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.

•Screening Patients for Bipolar Disorder

A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that Citalo is not approved for use in treating bipolar depression.

•Serotonin Syndrome

The development of a potentially life-threatening serotonin syndrome has been reported with SNRIs and SSRIs, including Citalo, alone but particularly with concomitant use of other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, trytophan, buspirone, and 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 and intravenous methylene blue).

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/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea)

Patients should be monitored for the emergence of serotonin syndrome.

The concomitant use of Citalo with MAOIs intended to treat psychiatric disorders is contraindicated. Citalo should also not be started in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue. All reports with methylene blue that provided information on the route of administration involved intravenous administration in the dose range of 1 mg/kg to 8 mg/kg.

No reports involved the administration of methylene blue by other routes (such as oral tablets or local tissue injection) or at lower doses. There may be circumstances when it is necessary to initiate treatment with an MAOI such as linezolid or intravenous methylene blue in a patient taking Citalo. Citalo should be discontinued before initiating treatment with the MAOI.

If concomitant use of Citalo with other serotonergic drugs including, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, buspirone, trytophan and St. John's Wort is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome particularly during treatment initiation and dose increases. Treatment with Citalo and any concomitant serotonergic agents should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated.

Citalo should be discontinued before initiating treatment with the MAOI.

If concomitant use of Citalo with other serotonergic drugs including, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, buspirone, trytophan and St. John's Wort is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome particularly during treatment initiation and dose increases. Treatment with Citalo and any concomitant serotonergic agents should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated.

- Patients with congestive heart failure, bradyarrhythmias, myocardial infarction or predisposition to hypokalemia or hypomagnesaemia because of concomitant illness or drugs, are at higher risk of developing Torsade de Pointes. Health Care Professionals should consider more frequent electrocardiogram (ECG) monitoring in patients with congestive heart failure, bradyarrhythmias.
- Hypokalemia and hypomagnesaemia should be corrected before administering citalopram. Electrolytes should be monitored as clinically indicated.
- Patients should contact a healthcare professional immediately if they experience signs and symptoms of an abnormal heart rate or rhythm while taking citalopram.
- Patients should be advised not to stop taking citalopram or change or reduce the dose without first consulting their healthcare professional, as withdrawal symptoms may occur when citalopram treatment is discontinued, particularly if this is abrupt.

PRECAUTIONS

General

Discontinuation of Treatment with Citalo

During marketing of Citalopram and other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms.

Patients should be monitored for these symptoms when discontinuing treatment with Citalo. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

Abnormal Bleeding

SSRIs and SNRIs, including Citalo, may increase the risk of bleeding events. Concomitant use of aspirin, non-steroidal anti-inflammatory drugs, warfarin, and other anticoagulants may add to the risk. Bleeding events related to SSRIs and SNRIs use have ranged from ecchymoses, hematomas, epistaxis, and petechiae to life-threatening hemorrhages. Patients should be cautioned about the risk of bleeding associated with the concomitant use of Citalo and NSAIDs, aspirin, or other drugs that affect coagulation.

Hyponatremia

Hyponatremia may occur as a result of treatment with SSRIs and SNRIs, including Citalo. In many cases, this hyponatremia appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH), and was reversible when Citalo was discontinued. Cases with serum sodium lower than 110 mmol/L have been reported. Elderly patients may be at greater risk of developing hyponatremia with SSRIs and SNRIs. Also, patients taking diuretics or who are otherwise volume depleted may be at greater risk. Discontinuation of Citalo should be considered in patients with symptomatic hyponatremia and appropriate medical intervention should be instituted.

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.

Activation of Mania/Hypomania

Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorders treated with other marketed antidepressants. As with all antidepressants, Citalo should be used cautiously in patients with a history of mania.

Seizures

Although anticonvulsant effects of citalopram have been observed in animal studies, Citalo has not been systematically evaluated in patients with a seizure disorder. These patients were excluded from clinical studies during the product's premarketing testing. Like other antidepressants, Citalo should be introduced with care in patients with a history of seizure disorder.

Interference with Cognitive and Motor Performance

Because any psychoactive drug may impair judgment, thinking, or motor skills, however, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Citalo therapy does not affect their ability to engage in such activities.

Use in Patients with Concomitant Illness

Due to the risk of QT prolongation, citalopram use should be avoided in patients with certain cardiac conditions, and ECG monitoring is advised if Citalo must be used in such patients. Electrolytes should be monitored in treating patients with diseases or conditions that cause hypokalemia or hypomagnesemia.

In subjects with hepatic impairment, citalopram clearance was decreased and plasma concentrations were increased. The use of Citalo in hepatically impaired patients should be approached with caution and a lower maximum dosage is recommended.

Because citalopram is extensively metabolized, excretion of unchanged drug in urine is a minor route of elimination. Until adequate numbers of patients with severe renal impairment have been evaluated during chronic treatment with Citalo, however, it should be used with caution in such patients.

If you have been told by your doctor that you have intolerance to some sugars; contact your doctor before taking this medicine.

Information for Patients

- **Physicians** are advised to discuss the following issues with patients for whom they prescribe Citalo.
- **Patients** should be cautioned about the risk of serotonin syndrome with the concomitant use of Citalo and triptans, tramadol or other serotonergic agents.
- **Although** in controlled studies citalopram has not been shown to impair psychomotor performance, any psychoactive drug may impair judgment, thinking, or motor skills, so patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that Citalo therapy does not affect their ability to engage in such activities.
- **Patients** should be told that, although citalopram has not been shown in experiments with normal subjects to increase the mental and motor skill impairments caused by alcohol, the concomitant use of Citalo and alcohol in depressed patients is not advised.
- **Patients** should be advised to inform their physician if they are taking, or plan to take, any prescription or over-the-counter drugs, as there is a potential for interactions.
- **Patients** should be cautioned about the concomitant use of Citalo and NSAIDs, aspirin, warfarin, or other drugs that affect coagulation since combined use of psychotropic drugs that interfere with serotonin reuptake and these agents has been associated with an increased risk of bleeding.
- **Patients should be advised** to notify their physician if they become pregnant or intend to become pregnant during therapy.
- **Patients should be advised** to notify their physician if they are breastfeeding an infant. While patients may notice improvement with Citalo therapy in 1 to 4 weeks, they should be advised to continue therapy as directed.
- **Prescribers** or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with Citalo and should counsel them in its appropriate use.

A patient Medication Guide about "Antidepressant Medicines, Depression and other Serious Mental Illness, and Suicidal Thoughts or Actions" is available for Citalo. The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents.

- **Patients** should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have. The complete text of the Medication Guide is reprinted at the end of this document.
- **Patients** should be advised of the following issues and asked to alert their prescriber if these occur while taking Citalo.

Clinical Worsening and Suicide Risk: Patients, their families, and their caregivers should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during antidepressant treatment and when the dose is adjusted up or down. Families and caregivers of patients should be advised to look for the emergence of such symptoms on a day to-day basis, since changes may be abrupt. Such symptoms should be reported to the patient's prescriber or health professional, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in the medication.

Laboratory Tests

There are no specific laboratory tests recommended.

DRUG INTERACTIONS

Serotonergic Drugs: See CONTRAINDICATIONS, WARNINGS, and DOSAGE AND ADMINISTRATION.

Triptans: There have been rare postmarketing reports of serotonin syndrome with use of an SSRI and a triptan if concomitant treatment of Citalo with a triptan is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases.

CNS Drugs: given the primary CNS effects of citalopram, caution should be used when it is taken in combination with other centrally acting drugs.

Alcohol: the use of alcohol by depressed patients taking Citalo is not recommended.

Monoamine Oxidase Inhibitors (MAOIs): See CONTRAINDICATIONS, WARNINGS and DOSAGE AND ADMINISTRATION.

Drugs That Interfere With Hemostasis (NSAIDs, Aspirin, Warfarin, etc.) - Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies of the case-control and cohort design that have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding have also shown that concurrent use of an NSAID or aspirin may potentiate the risk of bleeding. Altered anticoagulant effects, including increased bleeding, have been reported when SSRIs and SNRIs are coadministered with warfarin. Patients receiving warfarin therapy should be carefully monitored when Citalo is initiated or discontinued.

Cimetidine: Citalo 20 mg/day is the maximum recommended dose for patients taking concomitant cimetidine because of the risk of QT prolongation.

Digoxin: combined administration of Citalo and digoxin (single dose of 1 mg) did not significantly affect the pharmacokinetics of either citalopram or digoxin.

Lithium: because lithium may enhance the serotonergic effects of citalopram, caution should be exercised when Citalo and lithium are co-administered.

Pimozide: Citalopram did not alter the mean AUC or C of pimozide.

The mechanism of this pharmacodynamic interaction is not known.

Theophylline: Combined administration of Citalo (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.

Sumatriptan: If concomitant treatment with sumatriptan and an SSRI (e.g., fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram) is clinically warranted, appropriate observation of the patient is advised.

Warfarin:. Prothrombin time was increased by 5%, the clinical significance of which is unknown.

Carbamazepine: The possibility that carbamazepine might increase the clearance of citalopram should be considered if the two drugs are co-administered.

Triazolam: Combined administration of Citalo 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 Citalo (40 mg) and ketoconazole (200 mg) decreased the C and AUC of ketoconazole by 21% and 10%, respectively, and did not significantly affect the pharmacokinetics of citalopram.

CYP2C19 Inhibitors: Citalo 20 mg/day is the maximum recommended dose for patients taking concomitant CYP2C19 inhibitors because of the risk of QT prolongation.

Metoprolol: Co-administration of citalo 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.

Co-administration of Citalo (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. Nevertheless, caution is indicated in the co administration of TCAs with Citalo.

Electroconvulsive Therapy (ECT): there are no clinical studies of the combined use of electroconvulsive therapy (ECT) and Citalo.

PREGNANCY

Pregnancy Category C.

In animal reproduction studies, citalopram has been shown to have adverse effects on embryo/fetal and postnatal development, including teratogenic effects, when administered at doses greater than human therapeutic doses.

There are no adequate and well-controlled studies in pregnant women; therefore, citalopram should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pregnancy-Non-teratogenic Effects

Neonates exposed to Citalo and other SSRIs or serotonin and norepinephrine reuptake inhibitors (SNRIs), late in the 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 features are consistent with either a direct toxic effect of SSRIs and SNRIs or, possibly, a drug discontinuation syndrome. It should be noted that, in some cases, the clinical picture is consistent with serotonin syndrome.

When treating a pregnant woman with Citalo, the physician should carefully consider both the potential risks of taking an SSRI, along with the established benefits of treating depression with an antidepressant. This decision can only be made on a case by case basis.

Labor and Delivery

The effect of Citalo on labor and delivery in humans is unknown.

NURSING MOTHERS

As has been found to occur with many other drugs, citalopram is excreted in human breast milk. There have been two reports of infants experiencing excessive somnolence, decreased feeding, and weight loss in association with breastfeeding from a citalopram-treated mother; in one case, the infant was reported to recover completely upon discontinuation of citalopram by its mother and in the second case, no follow-up information was available. The decision whether to continue or discontinue either nursing or Citalo therapy should take into account the risks of citalopram exposure for the infant and the benefits of Citalo treatment for the mother.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

Decreased appetite and weight loss have been observed in association with the use of SSRIs. Consequently, regular monitoring of weight and growth should be performed in children and adolescents treated with Citalo.

Geriatric use

SSRIs and SNRIs, including Citalo, have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse event.

ADVERSE REACTIONS

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

Cardiovascular:

Frequent: tachycardia, postural hypotension, and hypotension.

Infrequent: hypertension, bradycardia, edema (extremities), angina pec toris, 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: 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: hayfever.

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, and 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.

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.

Overdosage

Human Experience

As with other SSRIs, a fatal outcome in a patient who has taken an overdose of citalopram has been rarely reported.

Symptoms most often accompanying citalopram overdose, alone or in combination with other drugs and/or alcohol, included dizziness, sweating, nausea, vomiting, tremor, somnolence, and sinus tachycardia. In more rare cases, observed symptoms included amnesia, confusion, coma, convulsions, hyperventilation, cyanosis, rhabdomyolysis, and ECG changes (including QTc prolongation, nodal rhythm, ventricular arrhythmia, and very rare cases of torsade de pointes).

Acute renal failure has been very rarely reported accompanying overdose.

Management of overdose

Establish and maintain an airway to ensure adequate ventilation and oxygenation. Gastric evacuation by lavage and use of activated charcoal should be considered. Careful observation and cardiac and vital sign monitoring are recommended, along with general symptomatic and supportive care. Due to the large volume of distribution of citalopram, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit. There are no specific antidotes for Citalo.

In managing overdose, consider the possibility of multiple-drug involvement.

The physician should consider contacting a poison control center for additional information on the treatment of any overdose

Dosage and administration

- Citalo should be administered once daily, in the morning or evening, with or without food.
- Citalopram should no longer be prescribed at doses greater than 40 mg per day.

Initial treatment

Citalo (citalopram HBr) should be administered at an initial dose of 20 mg once daily, with an increase to a maximum dose of 40 mg/day at an interval of no less than one week. Doses above 40 mg/day are not recommended due to the risk of QT prolongation. Additionally, the only study pertinent to dose response for effectiveness did not demonstrate an advantage for the 60 mg/day dose over the 40 mg/day dose.

Special populations

20 mg/day is the maximum recommended dose for patients who are greater than 60 years of age, patients with hepatic impairment, and for CYP2C19 poor metabolizers or those patients taking cimetidine or another CYP2C19 inhibitor, because these drugs factors lead to increased blood levels of citalopram, increasing the risk of QT interval prolongation and Torsade de Pointes. No dosage adjustment is necessary for patients with mild or moderate renal impairment. Citalo should be used with caution in patients with severe renal impairment.

Treatment of pregnant women during the third trimester

Neonates exposed to Citalo and other SSRIs or SNRIs, late in the third trimester, have developed complications requiring prolonged hospitalization, respiratory support, and tube feeding. When treating pregnant women with Citalo during the third trimester, the physician should carefully consider the potential risks and benefits of treatment.

Maintenance treatment

It is generally agreed that acute episodes of depression require several months or longer of sustained pharmacologic therapy.

It is not known whether the dose of citalopram needed to maintain euthymia is identical to the dose needed to induce remission.

If adverse reactions are bothersome, a decrease in dose to 20 mg/day can be considered.

Discontinuation of treatment with citalo

Symptoms associated with discontinuation of Citalopram and other SSRIs and SNRIs have been reported. Patients should be monitored for these symptoms when discontinuing treatment. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible.

If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

Switching a Patient To or From a Monoamine Oxidase Inhibitor (MAOI) Intended to Treat Psychiatric Disorders

At least 14 days should elapse between discontinuation of an MAOI intended to treat psychiatric disorders and initiation of therapy with Citalo. Conversely, at least 14 days should be allowed after stopping Citalo before starting an MAOI intended to treat psychiatric disorders.

Use of Citalo with Other MAOIs, Such as Linezolid or Methylene Blue

Do not start Citalo in a patient who is being treated with linezolid or intravenous methylene blue because there is an increased risk of serotonin syndrome.

In a patient who requires more urgent treatment of a psychiatric condition, other interventions, including hospitalization, should be considered.

In some cases, a patient already receiving Citalo therapy may require urgent treatment with linezolid or intravenous methylene blue. If acceptable alternatives to linezolid or intravenous methylene blue treatment are not available and the potential benefits of linezolid or intravenous methylene blue treatment are judged to outweigh the risks of serotonin syndrome in a particular patient, Citalo should be stopped promptly, and linezolid or intravenous methylene blue can be administered. The patient should be monitored for symptoms of serotonin syndrome for 2 weeks or until 24 hours after the last dose of linezolid or intravenous methylene blue, whichever comes first. Therapy with Citalo may be resumed 24 hours after the last dose of linezolid or intravenous methylene blue.

The risk of administering methylene blue by non-intravenous routes (such as oral tablets or by local injection) or in intravenous doses much lower than 1 mg/kg with Citalo is unclear. The clinician should, nevertheless, be aware of the possibility of emergent symptoms of serotonin syndrome with such use.

PACKAGE:

Citalo 20mg: carton box containing two (AL/PVC) strip each of 7 tablets and leaflets.

Citalo 40mg: Carton box containing 1, 2 or 3 (AL/ Transparent PVC)strip each of 10 tablets and leaflets.

Citalo oral solution 2mg/ml: carton box containing glass a bottle of 120ml +leaflet.

STORAGE: Stored at temperature not exceeding 30° C ,in dry place..

DELTA PHARMA S.A.E

Tenth of Ramadan City , A.R.E

DELTA PHARMA

سيتالو

(سيتالوبرام هيدروبروميد)

أقراص / محلول بالفم

• إقرا دليل الأدوية المرفق مع سيتالو قبل البدء في إستخدام الدواء، وفي كل مرة تعيد فيها إستخدام الدواء، فربما توجد معلومات جديدة.
• دليل الأدوية المرفق لا يغنى عن إستشارة طبيبك حول حالتك الصحية أو العلاج.
• التحدث مع الطبيب
• عليك التحدث إلى طبيبك إذا كان هناك شيء لا تفهمه أو تريد معرفة المزيد عنه.

١- ما هى أهم المعلومات التى يجب أن أعرفها عن سيتالو؟

ربما يسبب سيتالو وغيره من الأدوية المضادة للإكتئاب آثارجانبية خطيرة وتشمل:

• الأفكار الإنتحارية أو السلوك الإنتحارى:

– ربما يزيد سيتالو والأدوية الأخرى المضادة للإكتئاب من التفكير فى الإنتحار أو السلوك الإنتحارى في بعض الأطفال والمراهقين، أو الشباب في غضون الأشهر القليلة الأولى من العلاج أو عند تغييرالجرعة.
• الاكتئاب أو غيره من الأمراض العقلية الخطيرة هي أكثرالأسباب أهمية للأفكار الإنتحارية أو السلوك الإنتحارى.
• عليك مراقبة حدوث هذه التغييرات، كما يجب عليك الإتصال بمسئول الرعاية الصحية على الفور إذا لاحظت:
– تغييرات جديدة أو مفاجئة في المزاج، أو السلوك، أوالأفكار، أوالشعوروخاصة إذا كانت حادة.
– يجب الإنتباه لحدوث هذه التغييرات عند البدء فى إستخدام سيتالو أو عند تغيير الجرعة.
– يجب المحافظة على زيارة الطبيب للمتابعة كما يجب التواصل مع الطبيب بين الزيارات إذا كنت قلقاً بشأن الاعراض.

يجب عليك إبلاغ الطبيب إذا شعرت بالأعراض التالية أو الذهاب لمركز الطوارىء وخصوصاً إذا كانت جديدة أو مزعجة:

• محاولات الإنتحار.
• بناء على دوافع خطيرة.
• التصرفات العدوانية والعنيفة.
• التفكير فى الإنتحار أوالموت.
• حالات إكتئاب جديدة أو تفاقم للحالات السابقة.
• نوبات قلق جديدة أو تفاقم لحالات القلق أوحدوث نوبات خوف وهلع.
• الشعوربالهياج، والشعور بالضجر والتململ، والغضب والإضطراب.
• إضطراب النوم.
• زيادة النشاط أو كثرة الكلام على غير المعتاد.
• تغييرات أخرى غير معتادة فى السلوك أو المزاج.

إتصل بطبيبك فى الحال إذا شعرت بأى من الأعراض التالية، فقد يرتبط إستخدام سيتالو بحدوث آثار جانبية شديدة:

تغييرات فى نشاط القلب الكهربائى (إستطالة فى فترة كيو- تى وظاهرة تورساد دى بوينت)

هذه الأعراض قد تهدد الحياة، وتشمل الأعراض:

• ألم فى الصدر.
•سرعة أو بطء ضربات القلب.
• ضيق التنفس.
• الدوار أو الإغماء.

متلازمة السيروتونين

يمكن أن تكون هذه المتلازمة مهددة للحياة، وقد تشمل الأعراض:

• الهياج، والهلوسة، أو الغيبوبة أو تغييرات أخرى في الحالة العقلية.
• مشكلات فى التنسيق أو وخز العضلات (فرط ردود الفعل).
• تسابق ضربات القلب، إرتفاع أو إنخفاض ضربات القلب.
• الحمى او التعرق.
• الغثيان، القيىء أو الإسهال.
• تصلب العضلات.

الحساسية الشديدة

• إضطرابات فى التنفس.
• تورم الوجه، اللسان، العينين، أو الفم.
• طفح جلدي، بقع مصحوبة بالحكة أو البثور، وتوجد منفردة أو مصحوبة بالحمى أو آلام المفاصل.

نزيف غير معتاد

• قد يزيد سيتالو والأدوية الأخرى المضادة للإكتئاب من خطورة حدوث النزيف أو الكدمات، وخاصة إذا كانت تتناول أدوية سيولة الدم مثل الوارفارين، وهي مضادات الإلتهاب غيرالإستيرويدية (المسكنات) مثل ايبوبروفين أو نابروكسين)، أو الأسبرين.

النوبات أو التشنجات

نوبات الهوس

• زيادة الطاقة
• إضطراب شديد فى النوم.
• تسابق الافكار
• السلوكيات المندفعة
• أفكار كبيرة غير معتادة.
• السعادة المفرطة أو الإضطراب.
• كثرة أو سرعة الكلام أكثر من المعتاد.

تغييرات فى الشهية أو الوزن

يجب متابعة وزن وطول الأطفال والبالغين أثناء العلاج.

إنخفاض مستوى الصوديوم فى الدم

قد يكون كبار السن هم أكثرعرضة لإنخفاض مستوى الصوديوم فى الدم، وقد تشمل الأعراض:

• الصداع.
• الضعف أو الشعور بعدم الثبات.
• التشويش، ومشكلات فى التركيز أوالتفكير أو الذاكرة.

لا تتوقف عن تناول سيتالو دون إستشارة طبيبك أولاً؛ ذلك لأن التوقف السريع عن تناول سيتالو ربما يسبب أعراض خطيرة:

• القلق، الإضطراب، تقلب المزاج، ضيق الصدرأو تغيرفى عادات النوم.
• الصداع، التعرق، الغثيان، والدوار.
• إحساس يشبه الصدمة الكهربائية، الرعشة، التشويش.

٢- ما هو سيتالو؟

سيتالو هو دواء يوصف لعلاج الإكتئاب، لذا من المهم التحدث مع طبيبك حول مخاطرعلاج الإكتئاب وكذلك مخاطرعدم علاجه، كم يجب عليك مناقشة جميع خيارات العلاج مع طبيبك.

يستخدم سيتالو أيضا لعلاج:

• الإضطراب الإكتئابى الشديد.
• تخفيف الأعراض إذا كنت تعانى من نوبات الهلع.

عليك التحدث إلى طبيبك إذا كنت لاتعتقد أنك تشعر بالتحسن باستخدام سيتالو.

٣- من الذى لا يجب أن يستخدم سيتالو؟

لا تستخدم سيتالو:

• إذا كانت لديك حساسية لمادة سيتالوبرام هيدروبروميد، أو إيسيتالوبرام أوكسالات أو لأى مكون من مكونات الدواء.
• إذا كنت تتناول أدوية مثبطة لإنزيم مونوأمين أوكسيداز، فعليك التحقق من طبيبك أو الصيدلى عما إذا كنت تتناول أدوية مثبطة لإنزيم مونوأمين أوكسيداز وتشمل المضاد الحيوى لينزوليد.
• لا تتناول أدوية مثبطة لإنزيم مونوأمين أوكسيداز خلال أسبوعين من إيقاف إستخدام سيتالو ما لم يوصى الطبيب بذلك.
• لا تبدأ فى إستخدام سيتالو خلال آخر أسبوعين من إيقاف تناول الأدوية المثبطة لإنزيم مونوأمين أوكسيداز ما لم يوصى الطبيب بذلك.
• لا يستخدم سيتالوبرام مع الأدوية الأخرى المعروفة باطالة فترة (كيو- تى).
• يحظر إستخدام سيتالوبرام في المرضى الذين يعانون من متلازمة إطالة فترة(كيو تي) طويلة الخلقية.

ربما يتعرض المرضى الذين يتناولون سيتالو بالتزامن مع الأدوية المثبطة لإنزيم مونوأمين أوكسيداز إلى حدوث آثار جانبية خطيرة أو مهددة للحياة، لذا عليك طلب المساعدة الطبية فى الحال إذا شعرت بالأعراض التالية:

• حمى شديدة.
• تشنجات عضلية غير منضبطة.
• تصلب العضلات.
• تغييرات سريعة فى ضربات القلب أو ضغط الدم.
• التشويش.
• فقدان الوعى.
• تناول الدواء المضاد للذهان والذى يسمى بيموزيد؛ ربما يؤدى إلى حدوث آثار جانبية خطيرة بالقلب.
• إذا كان لديك مشكلة فى القلب بما فى ذلك متلازمة إستطالة فترة كيو- تى الخلقية.

٤- ما الذى ينبغى أن أخبر به طبيبى قبل تناول سيتالو؟

قبل البدء فى العلاج بسيتالو أخبر طبيبك:

• إذا كنت تتناول أدوية معينة مثل:
– الأدوية التى تستخدم لعلاج القلب.
– الأدوية التى تخفض مستوى البوتاسيوم أو المغنيسيوم فى الجسم.
– سيمتدين.
– أدوية التربتان التى تستخدم لعلاج الصداع النصفى.
– الأدوية التى تستخدم لعلاج التقلبات المزاجية، القلق، الإضطرابات الذهانية أو الفكرية، وتشمل الأدوية ثلاثية الحلقات، الليثيوم، مثبطات إعادة إمتصاص السيروتونين الإنتقائية، مثبطات إعادة إمتصاص السيروتونين والإبينفرين أو الأدوية المضادة للذهان.
– الترامادول.
– المكملات الغذائية التى تصرف من دون وصفة طبية مثل التربتوفان أو عشبة سانت جون.
• إذا كان لديك مشكلات فى الكبد.
• إذا كان لديك مشكلات فى الكلى.
• إذا كان لديك مشكلات فى القلب.
• إذا كنت مصاباً أو كنت تشعر بالنوبات والتشنجات.
•إذا كنت مصاباً بالإضطراب ثنائي القطب أو الهوس.
• إذا كان لديك إنخفاض فى مستوى الصوديوم بالدم.
• إذا كان لديك تاريخ مسبق للإصابة بالسكتة الدماغية.
• إذا كنت مصاباً بارتفاع ضغط الدم.
• إذا كانت لديك مشكلات فى النزف.
• إذا كانت المريضة حاملاً أو تنوى الحمل، فليس من المعروف ما إذا كان سيتالو يضر بالجنين، لذا يجب مناقشة فوائد ومخاطرعلاج الإكتئاب أثناء الحمل.
• إذا كانت المريضة فى فترة الرضاعة الطبيعية أو تنوى القيام بالرضاعة الطبيعية، فربما ينفذ سيتالو خلال لبن الأم؛ لذا يجب التحدث إلى طبيبك عن أفضل وسيلة لتغذية طفلك أثناء العلاج بسيتالو.
• اذا كنت تعلم مسبقاً بأن لديك عدم تحمل لبعض السكريات؛ فعليك الإتصال بطبيبك قبل تناول هذا الدواء.

أخبر طبيبك عن جميع الأدوية التى تتناولها بما فى ذلك الأدوية التى تصرف بوصفة طبية أو من دون وصفة طبية، الفيتامينات والمكملات الغذائية العشبية، فربما يتفاعل سيتالو مع بعض الأدوية، أو قد لا يعمل بشكل جيد، أو قد يسبب آثار جانبية خطيرة.

يمكن أن يخبرك طبيبك أوالصيدلى إذا كان آمناً إستخدام سيتالو بالتزامن مع أدوية أخرى.

لا تبدأ أو تتوقف عن إستخدام أى دواء أثناء العلاج بسيتالو دون إستشارة طبيبك.

لا تستخدم أى أدوية أخرى تحتوى على سيتالوبرام هيدروبروميد أو ايسيتالوبرام أوكسالات بما فيها ليكسابرو.

٥- كيف ينبغى أن أتناول سيتالو؟

• يجب أن تتناول سيتالو كما هو موصوف لك تماماً، ربما يحتاج طبيبك إلى تغيير جرعة سيتالو حتى الوصول للجرعة المناسبة لك.
• يمكن تناول سيتالو مع أو بدون الطعام.
• إذا نسيت أن تتناول جرعة من سيتالو، فعليك تناولها فور تذكرها، وإذا أوشك موعد الجرعة التالية فعليك تخطى الجرعة التى نسيتها وتناول الجرعة التالية فى وقتها المعتاد، ولا تتناول جرعتين من سيتالو فى ذات الوقت.
• إذا تناولت كمية كبيرة من سيتالو، فاتصل بطبيبك أو مركز للسموم للحصول على المساعدة الطبية

٦- ما الذى يجب أن أتجنبه أثناء العلاج بسيتالو؟

• سيتالو يمكن أن يسبب النعاس أو قد يؤثر على قدرتك على إتخاذ القرارات، أوعلى التفكير بوضوح، أوسرعة الإستجابة، لذا لا يجب عليك القيادة أو تشغيل الآلات الثقيلة أو القيام بأنشطة خطيرة حتى تعرف كيف يؤثر عليك سيتالو.
• لا تتناول المشروبات الكحولية أثناء العلاج بسيتالو.
• لا يجب أن يوصف سيتالوبرام بجرعات أكبر من ٤٠ مجم يومياً.
• ٢٠مجم يومياً هو الحد الأقصى للجرعة الموصى بها للمرضى الذين يعانون من الإختلال الكبدي، والمرضى الذين تزيد أعمارهم ٦٠ سنة، والذين يعانون من خلل فى التمثيل الغذائى لإنزيم CYP2C19، أو الذين يتناولون السيميتيدين بالتزامن مع سيتالو، وذلك لأن هذه الأدوية هى عوامل تؤدي إلى زيادة مستوى سيتالوبرام فى الدم، مما يزيد من خطورة إطالة فترة (كيو- تي) وظاهرة تورساد دى بوينت.
• المرضى الذين يعانون من قصور القلب الاحتقاني، بطء فى إيقاع، القلب إحتشاء عضلة القلب أو الذين لديهم ميل لنقص البوتاسيوم الدم أو للماغنسيوم فى الدم بسبب مرض مصاحب أو تناول أدوية، هم أكثر عرضة لخطورة حدوث ظاهرة تورساد دى بوينت؛ لذا ينبغى على مقدمى الرعاية الطبية المتابعة بإجراء رسم القلب الكهربائى، وذلك في المرضى الذين يعانون من قصور القلب الاحتقاني وبطء إيقاع القلب.
• يجب علاج نقص البوتاسيوم والماغنيسيوم فى الدم قبل العلاج بسيتالوبرام، لذا ينبغي ضبط الأملاح المعدنية كما هو مبين سريرياً.
• يجب على المرضى الاتصال بالطبيب فى الحال عند الشعوربعلامات وأعراض إضطراب معدل ضربات القلب أوإيقاع القلب أثناء العلاج بسيتالوبرام.
• يجب تحذيرالمرضى من إيقاف تناول سيتالوبرام أو تغيير أو تقليل الجرعة دون استشارة الطبيب أولاً. إذ من الممكن أن تحدث أعراض الإنسحاب عند التوقف عن العلاج سيتالوبرام، خاصة إذا كان هذا التوقف مفاجئ.

٧- ما هى الآثار الجانبية المحتملة لعقار سيتالو؟

ربما يسبب سيتالو آثارجانبية خطيرة، وتشمل (انظر فقرة " ما هى أهم المعلومات التى يجب أن أعرفها عن سيتالو؟".

الآثار الجانبية الشائعة التى تحدث مع سيتالو تشمل:

• الغثيان.
• النعاس.
• الضعف.
• الدوخة.
• الشعور بالقلق.
• إضطراب النوم.
• مشكلات جنسية.
• التعرق.
• الرعشة.
• عدم الشعور بالجوع.
• جفاف الفم.
• الإمساك.
• الإسهال.
• عدوى الجهاز التنفسى.
• التثاؤب.

آثار جانبية أخرى فى الأطفال والمراهقين تشمل:

• زيادة الشعور بالعطش.
• زيادة غير طبيعية فى حركة العضلات أو الهياج.
• نزيف الأنف.
• تكرارالتبول.
• غزارة فترات الحيض.
• إحتمال تباطؤ معدل النمو وتغير الوزن، لذا يجب رصد طول ووزن طفلك خلال فترة العلاج بسيتالو.

أخبر طبيبك إذا شعرت بأي آثار جانبية مزعجة أو إذا كانت لا تزول، فهذه ليست كل الآثار الجانبية المحتملة لسيتالو، و إسال طبيبك أو الصيدلى للحصول على مزيد من المعلومات.

٨- مكونات الدواء

المادة الفعالة:

سيتالو ٢٠مجم أقراص: يحتوى كل قرص مغلف على ٢٠مجم سيتالوبرام.
سيتالو ٤٠مجم أقراص: يحتوى كل قرص مغلف على ٤٠مجم سيتالوبرام.

المواد غير الفعالة:

سيتالو ٢٠مجم أقراص:

لاكتوز مونوهيدرات، ميكروكريستالين سيليلوز pH102، كولويدال سيليكون داى أوكسيد (إيروسيل ٢٠٠)، ماغنيسيوم إستيارات، كروس كارميلوز صوديوم.

سيتالو ٤٠مجم أقراص:

لاكتوزمونوهيدرات، ميكروكريستالين سيليلوز pH102، كولويدال سيليكون داى أوكسيد (إيروسيل ٢٠٠)، ماغنيسيوم إستيارات، كروس كارميلوز صوديوم.

الغلاف: هيدروكسى بروبيل ميثيل سيليلوز ٢٩١٠، تيتانيوم داى أوكسيد، بولى إيثيلين جليكول ٦٠٠٠.

سيتالو (٢مجم/١مللى) شراب:

المادة الفعالة:

يحتوى كل ١مللى من سيتالو شراب على٢مجم سيتالوبرام.

المواد غير الفعالة:

ميثيل بارابين، بروبيل بارابين، سوربيتول ٧٠٪، بروبيلين جليكول، بولى إيثيلين جليكول ٤٠٠، سكارين صوديوم، نكهة الموز ٢١٢٠٠٤، حمض ستريك، ماء نقى.

العبوة:

سيتالو ٢٠مجم: علبة كرتون تحتوى على شريطين (AL/PVC) بكل شريط ٧ أقراص مغلفة + نشرة داخلية.

سيتالو ٤٠مجم: علبة كرتون تحتوى على ٣،٢،١ شرائط (AL/Transparent PVC) بكل شريط ١٠ أقراص مغلفة + نشرة داخلية.

سيتالو (٢مجم/١مللى) شراب: علبة كرتون تحتوى على زجاجة سعة ١٢٠مللى + نشرة داخلية.

التخزين:

يحفظ عند درجة حرارة لاتزيد عن ٣٠ °مئوية فى مكان جاف.

شركة الدلتا للصناعات الدوائية ش.م.م
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