

**Celexa**

**Pharmacological Properties**

Celexa is effective as treatment for depression and for the specific reduction of symptoms associated with major depressive disorder (MDD) and generalized anxiety disorder (GAD). It is a potent inhibitor of the serotonin reuptake transporter (SERT) and is administered orally, which means it is absorbed into the bloodstream after being swallowed. Celexa is metabolized in the liver and primarily excreted in the urine. It has a plasma half-life of approximately 24 hours and is effective for up to 72 hours after a single dose.

**CLINICAL PHARMACOLOGY**

Celexa is contraindicated in patients with a hypersensitivity to citalopram or its components, and in patients with a known QT interval prolongation. It should be used cautiously in patients with a history of cardiac disease, including those with a recent history of myocardial infarction or unstable heart disease. It is also contraindicated in patients with a history of seizures, including those with a history of drug-induced seizures.

**PRECAUTIONS**

Drug Interactions

Citalopram is extensively metabolized by the cytochrome P450 (CYP) enzyme system, particularly by CYP2C19 and CYP3A4. Citalopram metabolism may be influenced by concomitant drug administration. For example, concomitant administration of citalopram and the CYP2C19 substrate, theophylline, resulted in a 50% decrease in the clearance of theophylline. Similarly, concomitant administration of citalopram and the CYP3A4 substrate, midazolam, resulted in a 50% decrease in the clearance of midazolam. Therefore, when administering citalopram, it is important to consider the potential for drug interactions and to monitor for adverse effects.

**ADVERSE REACTIONS**

The most common side effects of citalopram include nausea, vomiting, diarrhea, constipation, headache, and nervousness. More serious side effects include agitation, anxiety, panic attacks, insomnia, irritability, and suicidal ideation. Patients should be advised to seek medical attention if they experience any of these symptoms.

**Dosage and Administration**

Celexa is available in 20 mg tablets. The recommended dose is 20 mg daily, taken as a single dose in the morning or evening. The dose can be increased to 40 mg daily if necessary. Treatment should be continued for at least 6-12 weeks before determining that a patient has responded to treatment. Treatment discontinuation should be gradual to minimize withdrawal symptoms.

**CONTRAINDICATIONS**

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**Pregnancy**

Citalopram crosses the placenta and enters the fetal circulation. Therefore, it is recommended that citalopram should not be used during pregnancy. If citalopram use is necessary during pregnancy, patients should be advised to discontinue the drug as soon as possible.

**Pediatric Use**

Celexa has not been studied in children and adolescents. In postmarketing surveillance, psychiatric symptoms and behavior problems (e.g., agitation, aggressiveness) have been observed in children and adolescents who have been treated with selective serotonin reuptake inhibitors (SSRIs), including citalopram. Parents and caregivers should be advised to be alert for the emergence of such symptoms and to report them to their health care provider.

**Geriatric Use**

Older adults may be more susceptible to the adverse effects of citalopram, including agitation, anxiety, and suicidal ideation. Therefore, caution should be used when administering citalopram to elderly patients.

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2. Enter the appropriate answer.

3. You Should Watch for Certain Signs If Your Child Is Taking an Antidepressant

Contact your child's healthcare provider right away if your child exhibits any of the following signs for the first time, or if they seem worse, or worry you, your child, or your child's teacher:

- Thoughts about suicide or dying
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling very agitated or restless
- Panic attacks
- Difficulty sleeping (insomnia)
- New or worse irritability
- Acting aggressive, angry, or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking
- Other unusual changes in behavior or mood

Never let your child stop taking an antidepressant without first talking to his or her healthcare provider.

Stopping an antidepressant suddenly can cause other symptoms.

4. There are Benefits and Risks When Using Antidepressants

Antidepressants are used to treat depression and other illnesses. Depression and other illnesses can lead to suicide. In some children and teenagers, treatment with an antidepressant increases suicide thoughts or actions. It is important to talk all the risks of treating depression and also the risks of not treating it. You and your child should discuss all treatment choices with your healthcare provider, not just the use of antidepressants.

Other side effects can occur with antidepressants (see section below).

Of all the antidepressants, only fluoxetine (Prozac™) has been FDA approved to treat pediatric depression.

For obsessive compulsive disorder in children and teenagers, FDA has approved only fluoxetine (Prozac™), sertraline (Zoloft™), fluoxetine, and clomipramine (Anafranil™). Your healthcare provider may suggest other antidepressants based on the past experience of your child or your child's family members.

Is this all I need to know if my child is being prescribed an antidepressant? No. This is a warning about the risk of suicide. Other side effects can occur with antidepressants. Be sure to ask your healthcare provider to explain all the side effects of the particular drug he or she is prescribing. Also ask about drugs to avoid when taking antidepressant. Ask your healthcare provider or pharmacist where to find more information.

- Prozac® is a registered trademark of Eli Lilly and Company
- Zoloft® is a registered trademark of Pfizer Pharmaceuticals
- Anafranil® is a registered trademark of Macrillen Inc.

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

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St. Louis, MO 63045 USA

PRECAUTIONS: When treating pregnant women with Celexa during the third trimester, the physician should carefully consider whether the potential benefits outweigh the potential drug-related risks. The physician may consider leaving Celexa in the third trimester.

It is generally accepted that antidepressants can cause fetal abnormalities when administered to laboratory animals during organogenesis. Treatment with Celexa during pregnancy (10 mg or more/day) resulted in an increased incidence of malformations in the offspring of rats and rabbits. Thus, it is advisable to avoid the use of any antidepressant, particularly during the first trimester of pregnancy. However, the physician may decide that the benefits of the drug outweigh the potential risk to the fetus. When treating pregnant women with Celexa, the physician should be aware of the following:

- Events reported at twice the rate of controls include hypothyroidism, hypertension, and suicide. These events occurred in both depressed and nondepressed patients. The incidence rates of these events were higher in patients who were receiving antidepressants than in those who were not.
- Depression and other psychiatric disorders are common in children and adolescents, and also in pregnant women. Therefore, it is important to evaluate these conditions carefully in all patients, particularly when treating pregnant women with antidepressants.
- Antidepressants have been associated with a higher risk of suicidal thoughts and behaviors in children and adolescents treated with antidepressants. These data also suggest a lower risk of suicidal thoughts and behaviors in patients treated with placebo. However, the risk of suicidal thoughts and behaviors cannot be eliminated.
- It is important to continue the use of antidepressants even after the termination of treatment. If a patient is no longer benefiting from the medication, a gradual reduction in dosage may be necessary to avoid withdrawal symptoms. It is important to monitor the patient closely for any signs of withdrawal symptoms.
- Antidepressants have been associated with increased risk of bleeding. This risk is increased in patients on concurrent anticoagulant therapy or with a history of bleeding disorders.
- Antidepressants have been associated with a higher risk of cardiac dysrhythmias. These risks are increased in patients with a history of cardiac disease or other risk factors for cardiac dysrhythmias.
- Antidepressants have been associated with an increased risk of postpartum hemorrhage. This risk is increased in patients with a history of postpartum hemorrhage or with concurrent use of other medications that increase the risk of postpartum hemorrhage.
- Antidepressants have been associated with an increased risk of gastrointestinal perforation. This risk is increased in patients with a history of gastrointestinal perforation or with concurrent use of other medications that increase the risk of gastrointestinal perforation.
- Antidepressants have been associated with an increased risk of drug interactions. This risk is increased in patients with a history of drug interactions or with concurrent use of other medications that increase the risk of drug interactions.
- Antidepressants have been associated with an increased risk of adverse effects on embryo/fetal and postnatal development. This risk is increased in patients with a history of adverse effects on embryo/fetal and postnatal development or with concurrent use of other medications that increase the risk of adverse effects on embryo/fetal and postnatal development.
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