Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]CELEXA®

Citalopram Hydrobromide Tablets

This Patient Medication Information is written for the person who will be taking **CELEXA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **CELEXA**, talk to a healthcare professional.

Serious warnings and precautions box

New or worsened emotional or behaviour problems:

- When you first start taking CELEXA or when your dose is adjusted, you may feel worse instead of better. You may feel new or worsened feelings of agitation, hostility, anxiety, or impulsivity.
- During your treatment with CELEXA, it is important that you and your healthcare professional talk regularly about how you are feeling. They will closely monitor you for signs of new or worsened emotions or behaviours while you are taking CELEXA.
- You may find it helpful to tell a relative or close friend that you are depressed. Ask them to read this leaflet. You might ask them to tell you if they:
    - think your depression is getting worse, or
    - are worried about changes in your behaviour.
- If your depression worsens or you experience changes in your behaviour, tell your healthcare professional right away. Do not stop taking your medicine as it takes time for CELEXA to work.

Self-harm or Suicide

- Antidepressants, such as CELEXA, can increase the risk of suicidal thoughts or actions.
- If you have thoughts of harming or killing yourself at any time, tell your healthcare professional or go to a hospital right away. You will be closely observed by your healthcare professional in this situation.

What CELEXA is used for:

CELEXA is used to relieve the symptoms of depression in adults. Your healthcare professional will keep evaluating if CELEXA is still safe and effective for you if you take it for a long time.

How CELEXA works:

CELEXA is known as an antidepressant and belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs).

CELEXA works by increasing the levels of a chemical in the brain called serotonin.

The ingredients in CELEXA are:

Medicinal ingredients: citalopram hydrobromide

Non-medicinal ingredients: copolyvidone, corn starch, croscarmellose sodium, glycerin, lactose monohydrate, magnesium stearate, methylhydroxypropyl cellulose, microcrystalline cellulose, polyethylene glycol 400, titanium dioxide

CELEXA comes in the following dosage form:

Tablets: 10 mg, 20 mg or 40 mg citalopram (as citalopram hydrobromide).

Do not use CELEXA if:

- you are allergic to citalopram hydrobromide.
- you are allergic to any of the other ingredients in CELEXA or to a component of the container.
- you are also taking the medicine pimozide, used to treat schizophrenia.
- you are currently taking or have taken, within 14 days, medicines called monoamine oxidase antidepressants such as phenelzine sulphate, tranylcypromine or moclobemide, or other monoamine oxidase inhibitors such as linezolid, methylene blue, selegiline.
- you have been told that you have QT interval prolongation (abnormal electrical activity of the heart) or have been diagnosed with a condition called a congenital long QT syndrome.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CELEXA. Talk about any health conditions or problems you may have, including if you:

- have heart problems.
- have diabetes. CELEXA may make it more difficult to control your blood sugar.
- have liver or kidney problems.
- have or have had a seizure disorder.
- have or have had manic episodes or have been diagnosed with bipolar disorder.
- are receiving electroconvulsive therapy.
- have a bleeding disorder or have been told that you have low platelets.
- have a family history of QT/QTc prolongation (abnormal electrical activity of the heart).
- have electrolyte disturbances like low blood potassium, magnesium, or calcium levels or conditions that could lead to this such as vomiting, diarrhea, dehydration.
- had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis.
- are taking other antidepressants, triptans used to treat migraines, lithium, opioids (including to treat pain, or drug dependence), or drugs containing tryptophan.
- have habits of alcohol and /or street drug consumption.
- are taking St. John's Wort, an herbal product used to treat depression.

Other warnings you should know about:

- It is important that you and your healthcare professional talk regularly about how you are feeling while you are taking CELEXA.
- CELEXA should not be used in children and adolescents under 18 years of age.

Activation of Mania: Tell your healthcare professional if you have or have had manic episodes in the past or if you have been diagnosed with bipolar disorder. CELEXA should be used with caution if you have a history of manic episodes. Some patients with bipolar disorder (also known as manic depression) may enter into a manic phase when they start taking CELEXA. Tell your healthcare professional if you experience symptoms of mania such as excessive physical activity, overactive behaviour or thoughts, increased energy, trouble sleeping, racing thoughts, reckless behaviour, excessive happiness or irritability, talking more or faster than usual.

Bleeding Problems: Before taking CELEXA tell your healthcare professional if you have a bleeding disorder including low blood platelets. Drugs from the class that CELEXA belongs to may increase the chance of a bleeding event such as nose bleeds, bruising and even life threatening bleeding. This is more likely if you have a history of a bleeding disorder or are taking other drugs that are known to affect blood clotting. Talk to your healthcare professional about drugs that might increase bleeding.

Pregnancy: Before taking CELEXA, tell your healthcare professional if you are pregnant, think you might be pregnant or are planning to become pregnant. You should not take CELEXA if you are pregnant unless you and your healthcare professional have discussed the risks and decided that you should. Tell your healthcare professional right away if you become pregnant while taking CELEXA. If you take CELEXA near the end of your pregnancy, you could have heavy vaginal bleeding shortly after giving birth.

Effects on Newborns: Some newborn babies whose mothers took medications such as CELEXA during pregnancy have developed problems at birth. These problems include prolonged hospitalisation, breathing support and tube feeding. Symptoms can include:

- feeding and/or breathing difficulties
- bluish skin
- seizures
- body temperature changes
- vomiting
- low blood sugar
- tense or overly relaxed muscles
- vivid reflexes
- tremor
- jitteriness
- irritability
- sleeping difficulties and constant crying.

In most cases, these medications were taken during the third trimester of pregnancy. These symptoms are caused by the medication itself or from the effects of suddenly stopping the medication. These symptoms normally go away over time. However, if your baby experiences any of these symptoms, contact your healthcare professional as soon as you can.

Persistent Pulmonary Hypertension of the Newborn (PPHN): If you take CELEXA towards the end of your pregnancy, your newborn may be at risk of having a serious lung condition called Persistent Pulmonary Hypertension of the Newborn (PPHN). This causes breathing problems in newborns soon after birth. Newborn babies may breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your newborn baby, get immediate medical help for them.

Breastfeeding: Tell your healthcare professional if you are breastfeeding or planning to breastfeed. CELEXA is released into breast milk. It is not known if this is safe for your baby. You should not breastfeed a baby if you are taking CELEXA unless you and your healthcare professional have discussed the risks and decided that you should.

Effect on the electrical activity of the heart: CELEXA has an effect on the electrical activity of the heart known as QT/QTc prolongation (abnormal electrical activity of the heart). This can lead to disturbances in heart rhythm (arrhythmias/dysrhythmias) that could result in dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting or cardiac arrest and death. This is more likely in patients with risk factors, such as heart disease, heart attack, or in the presence of certain drugs that could interact with the activity of the heart. If you experience any symptoms of a possible heart rhythm disturbance (abnormal heart rate or rhythm), such as dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures, you should seek immediate medical attention.

Serotonin Toxicity or Neuroleptic malignant syndrome: Serotonin toxicity (also known as Serotonin syndrome): CELEXA can cause Serotonin toxicity, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop Serotonin toxicity if you take CELEXA with certain anti-depressants or migraine medications. Serotonin toxicity or Neuroleptic malignant syndrome symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma

Effects on Sexual Function: Taking medicines like CELEXA may cause symptoms of sexual dysfunction. In some cases these symptoms have continued after stopping CELEXA treatment. Talk to your healthcare professional if you experience symptoms such as a decrease in sexual desire, performance or satisfaction.

Risk of Bone Fractures: Taking CELEXA may increase your risk of breaking a bone if you are elderly, have osteoporosis or other risk factors for breaking a bone. You should take extra care to avoid falls especially if you get dizzy or have low blood pressure.

Angle-closure Glaucoma: CELEXA can cause dilation of the pupil. This may cause an acute glaucoma attack in an individual with narrow ocular angles. Having your eyes examined before you take CELEXA could help identify if you are at risk of having angle-closure glaucoma. Get immediate medical help if you experience:

- eye pain
- changes in vision
- swelling or redness in or around the eye.

Driving and using machines: CELEXA may impair your ability to drive or to use machines. Wait until you know how CELEXA affects you before driving or using machines. Do not drive or use machines if CELEXA impairs your ability to do so safely.

Discontinuation Symptoms: Contact your healthcare professional before stopping or reducing your dosage of CELEXA. If you stop or reduce the dosage of CELEXA abruptly, or if you miss a dose, you may experience symptoms such as dizziness, sleep disturbances, abnormal dreams, sensory disturbance like electric shock sensations, agitation, anxiety, headache, tremor (shakiness), nausea, vomiting. Tell your healthcare professional immediately if you have these or any other symptoms. Your healthcare professional may adjust the dosage of CELEXA to reduce the symptoms.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious drug interactions:

Serious drug interactions with CELEXA include:

- Monoamine oxidase inhibitors (MAOIs) such as phenelzine, tranylcypromine, moclobemide or selegiline, linezolid (as antibiotic) or Methylene blue (intravenous). **Do not use CELEXA if you are taking a MAOI, or have recently taken one in the last 14 days.**
- Pimozide.

The following may also interact with CELEXA:

- drugs to treat heart rhythm disturbances (antiarrhythmics)
- antipsychotics, used to treat schizophrenia
- opioids (including for pain, drug dependence or anesthesia) such as methadone, buprenorphine, tramadol, fentanyl, tapentadol, meperidine or pentazocine
- drugs to treat infections
- drugs to treat nausea and vomiting
- cancer drugs
- asthma drugs
- diuretics (water pills)
- carbamezepine, used to treat seizures
- other SSRIs e.g., Cipralex® (escitalopram) or any other antidepressant (e.g., imipramine, desipramine)
- lithium, used to treat mood disorder
- tryptophan, for sleep aid or treating anxiety
- cimetidine, for acidity problems
- triptans (e.g., sumatriptan, zolmitriptan, naratriptan), for Migraine
- fluconazole, Ketoconazole, Itraconazole, for treating fungal infection
- erythromycin, used to treat infections
- warfarin, used to prevent clot of blood
- omeprazole, used to treat stomach problems
- any herbal product such as St. John's Wort
- certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants (e.g., warfarin, dabigatran), acetylsalicylic acid (e.g., Aspirin®) and other non-steroidal anti-inflammatory drugs (ibuprofen)

- certain medicines used to treat cough, such as dextromethorphan

Avoid drinking alcohol while taking CELEXA.

How to take CELEXA:

- Take CELEXA exactly as your healthcare professional has told you.
- Swallow tablets whole with water. Do not chew them.
- You can take CELEXA with or without food.
- Take CELEXA once a day at the same time every day.
- Continue taking CELEXA even if you do not feel better. It may take several weeks for it to work and improvement may be gradual.
- Keep taking CELEXA for as long as your healthcare professional recommends. Do not stop taking CELEXA abruptly even if you feel better unless your healthcare professional has told you to.
- Never take more CELEXA than your healthcare professional has prescribed for you.
- Follow all instructions given to you by your healthcare professional.

Usual dose:

The usual dose is one 20 mg tablet once a day. Your healthcare professional might prescribe a lower dose if you are elderly, have liver problems or in other situations.

Overdose:

If you think you, or a person you are caring for, have taken too much CELEXA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you forget a dose, take the next dose as planned. Do not take a double dose to make up for a forgotten dose.

Possible side effects from using CELEXA:

These are not all the possible side effects you may have when taking CELEXA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Fatigue
- Dry mouth
- Increased sweating
- Tremor (shakiness)
- Nausea
- Diarrhea
- Somnolence (sleepiness)

- Ejaculation disorder

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Uncommon			
Bleeding problems: Bruising or bleeding from the skin, nose or other areas for longer than usual.		**X**	
Mania: Excessive physical activity, overactive behaviour or thoughts, increased energy, trouble sleeping, racing thoughts, reckless behaviour, excessive happiness or irritability, talking more or faster than usual.		**X**	
Rare			
Angle-closure Glaucoma (Increased pressure in eyes, change in vision such as hazy or blurred vision): Eye pain, change in vision, swelling or redness in or around the eye			**X**
Gastrointestinal bleeding: Vomiting blood, passing blood in stools		**X**	
Hypoglycemia (Low sugar level in blood)**:** Feeling shaky, sweating, chills and clamminess, irritability or impatience, confusion, fast heartbeat, feeling lightheaded or dizzy, nausea, seizure.		**X**	
Low sodium level in blood: Tiredness, weakness, confusion combined with achy, stiff or uncoordinated muscles		**X**	
Serotonin Toxicity and Neuroleptic Malignant Syndrome: A reaction which may cause feelings of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (>38 °C), or rigid muscles.			**X**
Very rare			

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Liver disorder: Nausea, vomiting, loss of appetite, itching, yellowing of the skin or eyes, dark urine		**X**	
New or Worsened Emotional or Behavioural Problems: Anxiety, hostility or impulsivity **Akathisia:** Feeling restless and unable to sit or stand still		**X**	
Seizures (fits)**:** Loss of consciousness with uncontrollable shaking			**X**
Self-harm and suicide: Have thoughts of harming or killing yourself			**X**
Unknown			
Heart rhythm disturbance (Abnormal heart rate or rhythm)**:** dizziness, palpitations (sensation of rapid, pounding or irregular heart beat), fainting, seizures			**X**
Postpartum haemorrhage (Heavy vaginal bleeding shortly after birth)**:** Excessive vaginal bleeding after child birth		**X**	
Serious skin reactions: Skin rash, redness of the skin, blistering of the lips, eyes or mouth, skin peeling, fever, chills, headache, cough, body aches			**X**
Symptoms after discontinuation or dose reduction: Dizziness, sleep disturbances, abnormal dreams, sensory disturbance like electric shock sensations, agitation, anxiety, headache, tremor (shakiness), nausea, vomiting		**X**	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store CELEXA at room temperature (15 - 30°C), in a dry place.

Keep out of reach and sight of children.

If you want more information about CELEXA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); or the manufacturer's website http://www.lundbeck.ca, or by calling 1-800-586-2325.

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