

Cipramil

Notice: user information

Cipramil 20 mg film-coated tablets citalopram

Please read this leaflet carefully before taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not give it to others. It may harm them, even if their signs of illness are the same as yours.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. WHAT IS CIPRAMIL AND WHAT IS IT USED FOR?

What is Cipramil ?

Cipramil is an antidepressant whose active ingredient is citalopram. It belongs to the group of selective serotonin reuptake inhibitors (SSRIs).

Serotonin is a substance present in everyone's brain. People who are depressed have lower serotonin levels than others. Cipramil and other SSRIs act on the serotonin system in the brain and help increase serotonin levels in the brain.

What is Cipramil used for ?

Cipramil contains citalopram and is used in the treatment of:

- major depressive episodes.
- panic disorder with or without agoraphobia.
- obsessive-compulsive disorder.

Your doctor may have prescribed Cipramil for other reasons. Contact your doctor if you have any questions about why you should take Cipramil.

2. WHAT YOU NEED TO KNOW BEFORE TAKING CIPRAMIL?

Never take Cipramil

- If you are allergic to the active substance or to any of the other ingredients of this medicine listed in section 6.
- If you are taking other medicines used to treat depression, called non-selective monoamine oxidase inhibitors (MAOIs), including phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine, moclobemide (a treatment for depression) and linezolid (an antibiotic). If you have taken any of these medicines, you should wait 14 days before starting Cipramil. One day after stopping moclobemide treatment may be sufficient.

After stopping treatment with Cipramil, you must wait 7 days before taking any of these medicines.

- If you have had or were born with an episode of heart rhythm disturbance (seen on an ECG, a test performed to assess how your heart is working).
- If you are taking treatments for heart rhythm disorders or treatments that could affect your heart rhythm (see section "Other medicines and Cipramil").

Warnings and precautions

Talk to your doctor or pharmacist before using Cipramil.

Tell your doctor about any other illnesses or medical history you may have, as they may need to be taken into account. In particular, tell your doctor:

- In case of a manic episode or panic disorder. Some manic-depressive patients may develop a manic phase. It is characterized by unusual and rapidly changing ideas, inappropriate joy, and excessive physical activity. If you experience this, contact your doctor.
- If you have liver disease or kidney disease, your doctor may need to adjust your medication doses.
- If you have diabetes. Treatment with Cipramil may alter your blood sugar levels. Adjustment of insulin and/or oral antidiabetic doses may be necessary.
- If you suffer from epilepsy. Treatment with Cipramil should be discontinued if epilepsy develops or if seizures increase in frequency (see section 4 "Possible side effects").
- If you have any conditions that may cause bleeding, or if you are pregnant (see "Pregnancy, breastfeeding and fertility").
- If your blood level of sodium, potassium or magnesium is too low.
- In case of electroshock treatment.
- In case of heart rhythm disorders. Such a disorder can be hereditary or appear spontaneously.
- If you have or have had heart problems or have recently had a heart attack.
- If you have a slow resting heart rate and/or know you are at risk of mineral deficiency due to severe and prolonged diarrhea or vomiting or taking diuretic medication.
- If you experience a rapid or irregular heartbeat, fainting, discomfort, or dizziness when standing up, as this may indicate an abnormal heart rhythm.
- If you have or have ever had eye problems, such as certain types of glaucoma (increased pressure inside the eye).
- If you cannot tolerate certain sugars, please also read the section "Cipramil contains lactose".
- If you are taking other medicines, please see the section "Other medicines and Cipramil".

Symptoms such as restlessness or difficulty sitting or standing still (akathisia) may also occur during the first few weeks of treatment. Tell your doctor immediately if you experience these symptoms.

Medicines like Cipramil (called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Suicidal thoughts and worsening of your depression or anxiety disorder

If you suffer from depression and/or anxiety disorders, you may have thoughts of harming yourself or killing yourself. These thoughts may be reinforced when you first start antidepressant treatment because these medications all take time to work, usually about two weeks, but sometimes longer.

The likelihood of having such thoughts is greater:

- If you have previously had suicidal thoughts or thoughts of harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behavior in adults under 25 years of age with psychiatric disorders who were treated with an antidepressant.

If you have persistent suicidal thoughts or thoughts of harming yourself, **contact your doctor or go to the hospital directly. You may find it helpful to tell a family member or friend** that you are suffering from depression or an anxiety disorder, and ask them to read this leaflet. You could ask them to alert you if they think your depression or anxiety is getting worse, or if changes in your behavior worry them.

Children and Adolescents

Cipramil should not be used in children and adolescents under 18 years of age. In addition, you should be aware that patients under 18 years of age, treated with this class of medication, have an increased risk of suicide attempts, suicidal thoughts and hostility (mainly aggression, rebellious behavior and anger). However, your doctor may prescribe Cipramil for patients under 18 years of age if he/she judges it to be in their best interest. If your doctor has prescribed Cipramil for a patient under 18 years of age and you wish to discuss this, do not hesitate to contact your doctor. You should inform your doctor if any of the above-mentioned symptoms appear or worsen in a patient under 18 years of age, treated with Cipramil. Long-term safety in relation to growth, maturation and mental and behavioral development has not been evaluated in this age group.

Specific information about your condition

As with other medications used to treat depression or related illnesses, improvement in your condition is not achieved immediately. Several weeks may pass before you feel any improvement.

In cases of panic disorder, improvement generally requires 2 to 4 weeks of treatment.

In the first few days of treatment, some patients experience an increase in anxiety, which disappears with continued treatment. It is therefore imperative to follow your doctor's advice. Do not stop treatment or change the dose without first speaking to your doctor.

Talk to your doctor or pharmacist before taking Cipramil.

Other medicines and Cipramil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medications can affect each other, which can sometimes cause serious side effects.

Tell your doctor if you are taking any of the following medications:

- **MAO inhibitors** (another group of drugs used to treat depression or Parkinson's disease) such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine, linezolid (an antibiotic), and moclobemide. If you have been taking any of these drugs, you should wait 14 days before starting treatment with Cipramil. You should wait one day after stopping treatment with moclobemide before starting treatment with Cipramil. After stopping treatment with Cipramil, you should wait 7 days before taking any of these drugs.
- Medicines containing selegiline (irreversible MAO-B inhibitors) because the risk of side effects is increased. The dose of selegiline should not exceed 10 mg per day. Selegiline is used in the treatment of Parkinson's disease.
- Lithium (used in the treatment of manic-depressive disorders) and **tryptophan**.
- Imipramine and **desipramine** (medicines used to treat depression). **Metoprolol** (used for high blood pressure and/or heart problems). Blood levels of metoprolol may increase, but no increase in therapeutic effects or adverse effects of metoprolol has been reported.
- Sumatriptan and similar drugs (used to treat migraines) and **tramadol** and similar drugs (opioids used as strong painkillers). These increase the risk of side effects. Consult your doctor if you experience any unusual symptoms while taking this combination.
- **Cimetidine, lansoprazole, and omeprazole** (used to treat stomach ulcers), fluconazole (used to treat fungal infections), fluvoxamine (antidepressant), and ticlopidine (used to reduce the risk of stroke). These medicines may increase blood levels of citalopram.
- **All medications that can affect blood clotting**, both as a therapeutic effect and as an adverse effect (e.g., some antipsychotics, acetylsalicylic acid (used as a painkiller), nonsteroidal anti-inflammatory drugs (used for arthritis), ticlopidine, and dipyridamole). These may slightly increase the risk of bleeding.
- **St. John's wort** (*Hypericum perforatum*, a herbal preparation for depressed mood). Combining Cipramil with herbal preparations containing St. John's wort may increase the risk of adverse effects.
- Mefloquine (used to treat malaria), **bupropion** (used to treat depression), and **tramadol** (used to treat severe pain) due to a possible risk of lowering the seizure threshold.
- Neuroleptics (drugs used in the treatment of schizophrenia and psychoses) due to a possible risk of lowering the seizure threshold, and **antidepressants**.
- Do not take Cipramil if you are taking medicines used to treat heart rhythm disorders or that may disrupt the heart rhythm, such as class IA and III **antiarrhythmic drugs, antipsychotics** (e.g., phenothiazine derivatives, pimozide, haloperidol), **tricyclic antidepressants**, **certain antimicrobial agents** (e.g., sparfloxacin, moxifloxacin, IV erythromycin, pentamidine, antimalarial treatments, especially halofantrine), **certain antihistamines** (astemizole, mizolastine). Contact your doctor or pharmacist if you have any questions about this.
- **Drugs that decrease blood levels of potassium or magnesium**, as these combinations increase the risk of potentially fatal arrhythmias.

Cipramil with food, drinks, and alcohol

You can take Cipramil with or without food. Cipramil does not enhance the effects of alcohol. However, it is advisable not to consume alcohol while taking Cipramil.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not use Cipramil if you are pregnant unless your doctor considers it absolutely necessary.

If you take Cipramil during the last three months of your pregnancy and up to the day of delivery, you should be aware that the following effects may occur in the newborn: breathing problems, blue skin discoloration, seizures, changes in body temperature, feeding difficulties, vomiting, low blood sugar, muscle contraction or relaxation, quick reflexes, tremors, irritability, lethargy, constant crying, drowsiness and sleep disturbances. If the newborn exhibits any of these symptoms, please contact your doctor immediately.

Make sure your midwife and/or doctor knows you are being treated with Cipramil. When used during pregnancy, particularly in the last 3 months of pregnancy, medicines such as Cipramil could increase the risk of a serious condition in newborns called persistent pulmonary hypertension of the newborn (PPHN), which causes the newborn to breathe faster and appear blue. These symptoms usually appear within the first 24 hours after birth. If this happens to your newborn, you should contact your midwife and/or doctor immediately.

If you take Cipramil in late pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth, particularly if you have a history of bleeding disorders. Your doctor or midwife should be informed that you are taking Cipramil so that they can advise you.

Breastfeeding

Breastfeeding is not recommended during treatment with Cipramil.

Fertility

In animal studies, citalopram has been shown to reduce sperm quality. Theoretically, this could affect fertility, however, no impact on human fertility has been observed to date.

Driving and using machines

Cipramil does not normally cause drowsiness. If you experience dizziness or drowsiness at the start of treatment, you should avoid driving or operating machinery until these symptoms have subsided.

Cipramil contains lactose and sodium.

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol (23 mg) of sodium per 20 mg, that is to say essentially 'sodium-free'.

3. HOW TO TAKE CIPRAMIL?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

Your doctor will determine your dose. Dosage can vary greatly from person to person.

The recommended dose is:

Adults

- Treatment of major depressive episodes

The usual dose is 20 mg (1 tablet) per day. This dose may be increased by your doctor up to a maximum of 40 mg (2 tablets) per day.

- Treatment of panic disorder with or without agoraphobia

Starting dose : 10 mg (½ tablet) per day.

After one week, your doctor may increase the dose to 20 mg (1 tablet) or 30 mg (1 and ½ tablets) per day.

Your doctor may increase the dose to a maximum of 40 mg (2 tablets) per day.

Some patients with panic disorder may experience worsening of anxiety symptoms during the first few days of antidepressant treatment. These symptoms subside with continued treatment (within 2 weeks). Panic disorder requires long-term treatment.

- Treatment of obsessive compulsive disorder

Starting dose: 20 mg (1 tablet) per day.

If necessary, your doctor may increase the dose up to a maximum of 40 mg (2 tablets) per day.

In obsessive-compulsive disorder, the therapeutic effect appears 2 to 4 weeks after the start of treatment and the condition improves with continued treatment.

Elderly patients (over 65 years)

The recommended starting dose is half (½ tablet) of the usual daily dose. Elderly patients should not take more than 20 mg (1 tablet) per day.

Patients at specific risk

Patients with impaired liver function should not take more than 20 mg (1 tablet) per day.

Use in children and adolescents

Do not give Cipramil to children or adolescents under 18 years of age. For further information, see section 'Warnings and precautions'.

Method and route of administration

Take Cipramil tablets once a day. Cipramil can be taken with or without food, at any time of day. Swallow the tablets with a little water. Do not chew the tablets because they have a bitter taste.

Duration of treatment

The duration of treatment can vary from person to person. Your doctor will tell you how long you should use Cipramil. Do not stop treatment prematurely.

As with other medicines for depression, panic disorder, or obsessive-compulsive disorder, it may take several weeks before you feel better.

Continue taking Cipramil for as long as your doctor thinks is necessary, even if you start to feel better. Your underlying illness may still be going on for some time, so symptoms may return if you stop treatment too early.

It is therefore recommended that you continue treatment for at least 6 months after you feel better. If you have had a history of recurrent depressive episodes, treatment may be extended to a year or more. Prolonged treatment, sometimes for several years, can prevent further depressive episodes from recurring.

If you take more Cipramil than you should

If you take too much Cipramil, contact your doctor, pharmacist, or the nearest Poison Control Center (070/245.245) or hospital emergency department immediately. Do this even if you do not feel any discomfort. Take the Cipramil pack with you if you go to the doctor or hospital.

Some of the signs of overdose can be life-threatening.

Symptoms of overdose include: nausea, vomiting, sweating, agitation, tremor, drowsiness, dizziness, seizures, coma, serotonin syndrome (see section 4 "Possible side effects?"), low or high blood pressure, fast or slow pulse, abnormal heart rhythm, rapid breathing (hyperventilation), dilated pupils, blue skin discoloration.

If you forget to take Cipramil

Do not double the dose to make up for a missed dose. If you forget to take a dose and remember before going to bed, take it immediately. Continue as usual the next day. If you only remember during the night or the next day, skip the missed dose and continue as usual.

If you stop taking Cipramil

Do not stop your treatment without contacting your doctor. At the end of your treatment, it is generally recommended to gradually reduce the dose of Cipramil over several weeks in consultation with your doctor.

Abruptly stopping this type of medication may cause withdrawal symptoms. These are usually mild and transient.

Dizziness, tingling sensations, tremors, sleep disturbances (nightmares, insomnia or intense dreams), agitation or anxiety, nausea and/or vomiting, confusion, sweating, headache, diarrhea, palpitations, feeling emotional, irritability and visual disturbances. For this reason, it is generally recommended to gradually reduce the dose of Cipramil over several weeks. Contact your doctor if you wish to stop treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some patients have reported the following severe side effects:

Warning! If you experience any of the following side effects you should stop treatment and contact your doctor immediately:

- High fever, agitation, confusion, tremors, and sudden muscle twitching. These may be signs of a rare disorder called serotonin syndrome. This syndrome has been reported with several antidepressant medications.
- If you experience swelling of the skin, tongue, lips or face or if you have difficulty breathing or swallowing (a severe allergic reaction).
- Abnormal bleeding, including gastrointestinal bleeding.

Rare but serious side effect (affects less than 1 in 1,000 people)

Warning! If you experience any of the following side effects you must stop treatment and contact your doctor immediately:

- Hyponatremia: Decreased sodium concentration in the blood with feelings of fatigue, confusion and muscle contractions.
- Rapid or irregular heartbeat, fainting which could be signs of Torsade de Pointes (a life-threatening event).

However, side effects are generally mild and usually subside after a few days of treatment. Be aware that some of these effects may also be symptoms of your illness and will therefore diminish as you begin to feel better.

Tell your doctor if you experience any bothersome side effects or if they last more than two weeks.

Very common (affects more than 1 in 10 people)

- Dry mouth. A dry mouth increases the risk of tooth decay. In this case, it is advisable to brush your teeth more than usual.
- Insomnia
- Drowsiness
- Nausea (feeling unwell)
- Excessive sweating
- Headaches

Common (affects less than 1 in 10 people)

- Hustle
- Decreased appetite, weight loss
- Yawning, fatigue
- Diarrhea, constipation
- Vomiting
- Dizzying sensations
- Tingling sensations in the feet and/or hands
- Itching
- Decreased libido
- Anxiety
- Nervousness
- Confusion, abnormal dreams, attention disorders
- Tremors
- Fever
- Hearing a repetitive sound
- Joint and/or muscle pain
- In men: impotence, ejaculation disorders
- In women: difficulty reaching orgasm

Uncommon (affects less than 1 in 100 people)

- Increased appetite, weight gain
- Aggressiveness
- Depersonalization
- Hallucination
- Mania
- Syncope
- Enlarged pupil
- Fast or slow heart rate
- Hair loss
- Rash
- Urticarial rash (hives), hypersensitivity to light
- Dark spots under the skin (bruise sensitivity)
- Unexpected vaginal bleeding

- Difficulty urinating (urinary retention)
- Swelling of the arms or legs
- Urinary hesitancy, decreased urination

Rare (affects less than 1 in 1,000 people)

- Convulsions
- Involuntary movements
- Taste disorders
- Bleeding
- Hepatitis
- Blood sodium level too low

Frequency not known (cannot be estimated from the available data)

- Allergic reactions including skin rash
- Involuntary muscle movements or muscle stiffness
- Decrease in the number of platelets in the blood (risk of bleeding and bruising)
- Nosebleeds, gastrointestinal bleeding
- Severe allergic reaction with difficulty breathing and dizziness
- Increased urine volume (insufficient secretion of ADH)
- Hypokalemia: decreased potassium concentration in the blood with muscle weakness
- Muscle contractions
- Akathisia: involuntary movements
- Minor subcutaneous bleeding and bleeding from mucous membranes (bruising)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breastfeeding and fertility' in section 2 for further information
- Panic attacks
- Hustle
- Grinding of teeth
- Vision problems
- Blood pressure drops when standing up
- Sudden swelling of the skin and mucous membranes
- Painful erections
- Increased blood levels of the hormone prolactin
- Liver test disturbances
- Suicidal thoughts and suicidal behaviors, see "Warnings and precautions" section
- Milk flow in men and non-breastfeeding women
- Irregularity of the menstrual cycle
- Change in heart rate, measured by electrocardiogram (QT prolongation)
- An increased risk of bone fractures has been observed in patients taking this class of drugs.

Reporting of side effects

If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects via:

Belgium:

Federal Agency for Medicines and Health Products

www.afmps.be

Vigilance Division:

Website: www.notifieruneffetindesirable.be

e-mail: adr@fagg-afmps.be

Luxembourg:

Regional Pharmacovigilance Centre of Nancy or Pharmacy and Medicines Division of the Health Directorate

Website: www.guichet.lu/pharmacovigilance

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CIPRAMIL?

Keep out of sight and reach of children.
This medicine does not require any special storage precautions.

Do not use this medicine after the expiry date which is stated on the label and packaging after "EXP". The expiry date refers to the last day of that month.

Do not dispose of any medications via wastewater or household waste. Ask your pharmacist how to dispose of medications you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What Cipramil contains

The active ingredient is citalopram, in the form of hydrobromide. Each tablet contains 20 mg of citalopram in the form of hydrobromide.

The other ingredients are:

Tablet core : maize starch, lactose monohydrate, microcrystalline cellulose, copovidone, glycerol 85%, croscarmellose sodium, magnesium stearate.

Coating : hypromellose 5, macrogol 400. Colour : titanium dioxide (E171).

What Cipramil looks like and contents of the outer packaging

White, oval, film-coated tablets, scored and marked with 'C' and 'N' on either side of the score line on one side of the tablet.

Cipramil is available in transparent blisters with 28, 56 or 98 tablets in a cardboard box and 28 or 56 tablets in unit dosages.

Not all presentations listed may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Lundbeck sa - Stephanie Square Centre - Avenue Louise 65/11 - 1050 Brussels

Manufacturer

H. Lundbeck A/S – Ottiliavej 9 – 2500 Valby – Denmark

Conditions of dispensing

Medication subject to medical prescription.

Marketing authorization number:

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LU: 1997114272

The last date this notice was approved is 01/2025.